# Thoracic Drains in Intensive Care Units. Comparison of Seldinger and surgical methods (Drain-ICU trial): study protocol for a prospective randomized controlled trial

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UFR DE MÉDECINE ET DES PROFESSIONS PARAMÉDICALES

THÈSE D'EXERCICE

pour le

DIPLÔME D'ÉTAT DE DOCTEUR EN MÉDECINE

par

PAQUETTE, Bertille Catherine Gilberte

Présentée et soutenue publiquement le 01/04/2021

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## REMERCIEMENTS

**Monsieur le Professeur BAZIN,** vous me faites l'honneur de présider ce jury de thèse et je vous en remercie. Vous avez été bienveillant, accessible et disponible tout au long de ces années d'internat. Je vous remercie pour cette formation de qualité. Veuillez trouver dans ce rôle de président du jury l'expression de ma profonde reconnaissance et de mon respect.

**Monsieur le Docteur GODET,** je te remercie profondément de m'avoir acceptée dans ce projet lorsqu'il était encore débutant. Après quelques années d'un parcours parfois semé d'embûches, nous avons réuni une équipe, une dream team. Ta prévenance et ta disponibilité nycthémérale ont permis d'alléger les aspects les plus fastidieux de ce travail, et c'est avec grand plaisir que je le poursuivrai à tes côtés. Je te remercie également pour la part que tu as pris dans ma formation, aussi bien sur le plan humain que médical et théorique. Je ne devrais pas te remercier pour ces cours et interrogatoires en garde, au creux de la nuit, n'empêche qu'ils ont su fixer nombre de notions dans mon esprit pourtant ensommeillé. Au final, plus que tout, je te remercie pour la confiance que tu as placée en moi.

**Monsieur le Professeur FUTIER,** je te remercie pour ta présence tout au long de cet internat. Ton enseignement avec notamment ces longs moments passés dans les chambres à régler les respirateurs, tes dessins sur des feuilles d'essuie-tout, et puis ton sens du style et ton accessibilité qui se traduit souvent par des expressions colorées, ta prodigalité en capsules de café et en explications scientifiques. Malgré ce tutoiement, et certainement encore plus grâce à lui, je te respecte profondément.

**Monsieur le Docteur GUERIN,** je suis honorée de te compter parmi les membres de mon jury. J'espère que ce travail apportera une réponse à la question de ce « crunch » que tu as soulevée il y a quelques années. Tes enseignements ont contribué à former mon esprit critique, tu m'as appris l'économie des mots et des compresses. Je suis honorée d'avoir la chance de travailler à tes côtés dans le futur, j'espère me régaler encore en staff ou dans tes mails de ta verve parfois bougonne, parfois inspirée, souvent inspirante.

**Monsieur le Docteur GALVAING,** je te remercie d'avoir accepté d'apporter ton expertise dans le jugement de ce travail. Ces quelques mois à tes côtés en chirurgie thoracique ont été riches en enseignements. Je t'assure que c'est sans plaisir sadique mais uniquement avec inexpérience que je vous ai fait subir mes talents de DJ pendant ces longues heures sur le champ opératoire. Permets-moi de régler mes dettes concernant les paris sur les quantités de liquide pleural en champagne. Je suis honorée de ta présence.

## REMERCIEMENTS

A mes **parents**, pour leur éducation bienveillante et attentionnée,
A mes **frères**, que je surkiffe malgré la distance et les bêtises qu'ils apprennent à ma fille,
A mes grands-parents, **Laurent et Lucienne**, **Denis et Lily**,
A Gabrielle, dite **Gaby**. Vive, pour ne pas dire remuante, tes éclats de rire effacent mes soucis et me permettent de recentrer mes priorités,
A **Marcelle** et bientôt **Simone**, compagnons à fourrure,
A Pierre, dit **Pedro**. Désolée pour ces 3 râteaux consécutifs initiaux, le premier à J2 du début de l'internat montluçonnais... Mon Bienheureux.
A ses parents, **Claire et Philippe**, et son frère **François, Tata Lite et Jean Michel**, pour leur accueil chaleureux,

A tous ceux qui ont essayé de me détourner des études de médecine au lycée car j'avais la phobie du sang : je vous emmerde.

A **Valentin**, mon ami depuis la sortie de l'enfance,
A l'équipe bobo-cool de l'externat : **Camille, JMDSA, Baptiste** et puis **Angel**. Bœufs dans des cave, films indépendants et discussions sur le sens de la vie jusqu'à l'aurore,
A **Marion** et la douce **Alice**,
A ma **Léo** et nos après-midi ensoleillées au bord du lac St Point. Nos discussions itératives au fil des ans. Le bonheur de te voir t'épanouir à nouveau,
A **Julien**, pour ton HSV-1. Espèce de doux dingue lunatique. Ton dernier repas (Jacques Brel), mains dans les poches, et son goût qui reste amer après toutes ces années,
A **Muche,** qui était un berger,
A **Jux,** co-équipière (de grimpe, de folie). Nos genoux écorchés et nos ampoules aux mains, nos nombreux TC sans PC, nos randos hors des chemins tracés, nos nuits en camion et à la belle étoile,
A **Roubaix**,
Au **Dr Fred Gauthier**, qui m'a demandé un jour de faire vivre éternellement ma part d'enfant si vive et de ne jamais la laisser mourir dans la rigueur froide et sérieuse de la médecine,

A la **promo ZEP**, équipe de débiles aux prénoms improbables. **PA, Didou, Ugo, FX, Ridvan, Loris, Crispouille, Zach, Julie**,
A la **Bitcherie**, groupe informel de gonzesses admirables. **Clouchette, Didine, Dalinounette, Katiaounette, GoMar, Lynou**,
A **Margot**, pour son idéal d'adelphité,
Aux **internes du DAR**, croisés en stage ou en soirées.
A **Jean-Guy** et son surnom qui lui restera pour la fin de son internat,
Aux barbeucs hebdomadaires avec **BB, chérie-dinde, Dr Lulu**, **Camillou** et **Rond**,

A **Montluçon**, au Perceval, au bourbonnais libre et indépendant, aux buses et vous reprendrez bien une tranche de pâté ?
A **Nelly** et **Bouchon**. **A l'équipe moulinoise**,
A **Thérèse, Sylvie, Jocelyne, Marie Kiki** et **Mathilde**,
Aux **chefs clermontois**, du bloc et de réanimation,
Aux **équipes du bloc central GM et NHE, du CJP**.

Et surtout, **à tous ces gens** qui ont le smile quand on les croise, qui rassurent et apaisent, qui soignent à la fois avec technicité et humanité. A ceux qui adoucissent nos journées, à ces équipes qui donnent envie de se lever le matin pour aller bosser. Tchao l'internat et salut l'artiste !

**Sérendipité.**

*A L'Affiche Rouge (Léo Férré), Frühling in Paris (Rammstein), Slow (Leonard Cohen), Kyrie Eleison (Bachar Mar-Kalifé), Bang Bang (Monophonics), Sinermann (Nina Simone), Vice et Versa (Les Inconnus), El Beach (The Limiñanas), My Type (Saint Motel), I Was Born A Cancer (Jack The Ripper), Zorba The Greek (Murphy & Hugues), Hey Boy Hey Girl (Chemical Brothers), C'Était Bien Au Petit Bal Perdu (Bourvil), La Forêt (Lescop), Red Right Hand (Nick Cave & The Bad Seeds).*

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## LIST OF ABBREVIATIONS

BPS: Behavioral Pain Scale

BPS-NI: Behavioral Pain Scale Non-intubated

BTS: British Thoracic Society

CONSORT: Consolidated Standards of Reporting Trials

CPP: Comité de Protection des Personnes (ethics comitee)

CT-scan: Computed tomography scan

DSMB: Independent Data and Safety Monitoring Board

eCRF: electronic Case Report Form

EMA: European Medicines Agency

ESICM: European Society of Intensive Care Medicine

$FiO_2$: Fraction of inspired oxygen

Fr: French

ICU: Intensive Care Units

mITT: modified Intent to Treat

NPSA: UK National Patient Safety Agency

RASS: Richmond Agitation and Sedation Scale

RCT: Randomized Controlled Trial

SAPS II: Simplified Acute Physiologic Score II

SOFA: Sequential Organ Failure Assessment

SPIRIT: Standard Protocol Items : Recommendations for Interventional Trials

$SpO_2$: Pulsed Saturation of dioxygen

VRS: Verbal Rating Scale

# 1. INTRODUCTION

## 1.1 Background

The need for chest drainage and insertion of a chest tube are frequently required in intensive care units (ICU). Indications and clinical situations include infectious diseases (empyema, pleuro-pneumonia), hemorrhages (post-traumatic or spontaneous), malignant pleural effusions, transudative effusions (cardiac dysfunction, cirrhosis, anasarca...) and pneumothoraxes [1]. Pleural effusions and pneumothoraxes are common secondary care conditions that accounted for more than 29,000 admissions in the 2011-2012 period in the National Health Service in England [2]. Although first-line treatment is mostly conservative, intensivists, anesthesiologists and emergency physicians, regularly have to deal with chest drainage.

Two methods with different drain sizes are usually validated based on physicians' habits and available devices. First, small-bore chest drains that are inserted by the "Seldinger technique". A needle is inserted in the intercostal space and a fluid (liquid or gas) aspiration confirms correct position, occasionally after ultrasound guidance. A metal guidewire is inserted through the needle, which is then removed. A dilator is then slipped over the guidewire to dilate skin and subcutaneous tissues. The drain is finally inserted over the guidewire, before its removal and drain connection to vacuum system. Second, large-bore drains are inserted after progressive chest wall blunt-dissection (the so-called "surgical technique"). Those drains are usually trocard-fitted. Literature highlights numerous complications associated with chest drainage whatever the technique used. In the early 2000s, improved training and the advent of small-caliber chest drains inserted by Seldinger technique was expected to lead to lower complications' rates. Unfortunately, descriptions of serious adverse events continued and in 2008 the UK National Patient Safety Agency (NPSA) published a report with recommendations for safer practices [3].

Complications associated with chest drain insertion remain infrequent, ranging from 0 to 8% [1]. Small and large drains have specific common complications: empyema and insertion site infections, pain, malposition and drain plugging. Small diameter drains carry a falling risk, while larger drains are specifically associated with potentially serious visceral injuries.

Complications have been reported to be larger when using large-caliber thoracic drains inserted by the surgical technique in trauma patients [4]. Small-caliber thoracic drains inserted by Seldinger technique using ultrasound location and guidance are plebiscited by British Thoracic Society (BTS) guidelines in 2010 [1]. No French recommendations have been published except for early thoracic trauma in 2015 [5].

A recent international survey endorsed by the ESICM (European Society of Intensive Care Medicine) has reported wide differences in the management of primary spontaneous pneumothoraxes among intensivists [6], despite published recommendations [1]. A recent phone survey has evaluated the evolution of chest tube insertion techniques among French intensivists between 2007 and 2012 [7]. Main conclusion is that French practice significantly differs from British guidelines. Between 2007 and 2012, median percentage of chest tubes inserted with Joly trocar surgical technique remained high (27% *versus* 30%, p=0.383), while chest tubes inserted with Monod trocar significantly decreased (41% *versus* 29%, p=0.012). Meanwhile, small diameter drains were more frequently inserted using Seldinger technique (10% versus 22%, p=0.005).

These practices differ from BTS guidelines which recommend drainage of pneumothorax and non-traumatic pleural effusions with small diameter (< 20 French (Fr)) drains using Seldinger technique [1]. Large diameter drains (> 20 Fr) inserted with progressive chest wall blunt dissection should only be used in cases of trauma or empyema (to potentially avoid secondary obstruction), not supported by recent results from a retrospective observational study [8]. Finally,

French survey reports chest drains were mainly surgically inserted [7], bearing in mind that Monod trocar might present with the largest visceral injury risk.

Type of chest drain used might depend on medical or surgical conditions associated with drainage indication, and experience and/or operator habits. Small-bore chest tubes might be preferred for simple pleural effusions or pneumothoraxes [9-11], while thick-suspected effusions (empyema or blood) would urge the use of large-bore tubes [12], especially after thoracic trauma [13], despite recent retrospective data concluding on the potential non-inferiority of 14Fr pigtail catheters compared to larger chest tubes [14]. Results of retrospective or prospective small studies might suggest the polyvalent and efficient use of small-bore chest tubes in any of these indications without increasing complications (drain blockage), with reduced pain scores [9].

Therapeutic equivalence of small-caliber drains inserted by Seldinger method with large-diameter drains surgically inserted remains unknown to date. Preferential use of smaller drains inserted using Seldinger technique was thought to render chest drainage procedure safer [4], without any supportive strong evidence [15].

To our knowledge, no RCT (Randomized Controlled Trial) has been published or is in progress on the subject of chest drainage in ICUs (query ClinicalTrials.gov, 02/28/2021). Currently available data come from low level of evidence small observational or retrospective studies. We therefore propose to conduct a large multicenter RCT to compare chest tube insertion techniques in ICU patients.

### 1.2 Objectives

#### *Primary objective*

Primary objective is to compare tolerance of thoracic drainage in ICU performed either by Seldinger technique (small drains) or by surgical-like technique (larger drains).

***Secondary objectives***

Secondary objectives include comparison of effectiveness of both techniques, respective costs estimates, difficulties encountered, associated practices (ultrasound-tracking and -guidance, implantation site, operator skills) and to determine secondary determinants of tolerance and efficacy.

### 1.3 Trial Design

The Thoracic Drains in Intensive Care Units (Drain-ICU) study is an investigator initiated, open-labeled, multicenter, randomized controlled two-arm trial.

### 1.4 CONSORT Diagram

Figure 1 shows CONSORT (Consolidated Standards of Reporting Trials) diagram of Drain-ICU trial.

## 2. METHODS & DESIGN

This manuscript was written in accordance with SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) guidelines [16].

### 2.1 Study Setting

Drain-ICU study involves to date 7 mixed medico-surgical ICUs in France (Clermont-Ferrand (5 ICUs), Montluçon and Marseille) with an expected total of participating centers of about 30.

### 2.2 Eligibility criteria

#### *Inclusion criteria*

Patients must be adults (>18), with social security insurance, admitted in a participating ICU, and requiring pleural drainage, semi-urgent or planned.

#### *Non-inclusion criteria*

Patients fulfilling one or more of the following criteria will not be included: under curatorship or guardianship, pregnant or breastfeeding women, refusal to participate or continue participation in the study, previous study inclusion, presenting with a severe or uncompensated coagulation disorder evaluated as incompatible with chest drainage, an acute chest trauma (< 6 hours), or a compressive pneumothorax requiring immediate needle exsufflation, and a previous chest drainage (whatever the technique used) performed during the same ICU stay.

### 2.3 Interventions

Patients requiring chest drainage are screened for inclusion criteria. In the absence of non-inclusion criteria, an online computer-based software randomization will be conducted, allowing patient's allocation to either Seldinger or surgical-like drainage group. Investigators will use drains available at each participating centers. These medical devices will not be studied *per se*,

but their characteristics will be collected. *A priori* defined judgment criteria will be analyzed before, during and after drainage procedure.

Procedure will be performed following habits of study investigators at participating centers. In general, use of available guidelines and recommendations will be encouraged [1, 5].

Following steps and related data will be recorded:

1. Patient installation;
2. Ultrasound use to determine pleural effusion characteristics, anticipated volume and drainage site;
3. Large and rigorous skin disinfection according to sites protocols, followed by sterile sheets application;
4. Local anesthesia according to physicians habits;
5. Start of a stopwatch at first skin effraction, either with Tuohy needle (Seldinger group) or scalpel (surgical-like group);
6. Chest tube insertion according to the randomization group using full aseptic technique;
7. End of the stopwatch after proper drain insertion, and before definitive attachment and connection to vacuum system;
8. Tube fixing with sutures, sterile dressings applications and connection to suction system with vacuum depression level (in $cmH_2O$).

Patient's sedation and analgesia will be handled by site investigators following local protocols and recorded in the electronic case report form (eCRF). Sedation and analgesia will be encouraged to be maintained throughout the procedure unless pain scores are high or raising : Behavioral Pain Scale (BPS) > 6 for intubated patients [17, 18] or Behavioral Pain Scale Non-Intubated (BPS-NI) > 6 for not intubated and not communicating patients [19], or a Verbal Rating Scale (VRS) > 3 in conscious and communicating patients [20, 21]. Boluses of sedation or analgesia and/or change in rates of administration will be collected.

Included patients will be cared for according to international recommendations throughout their ICU stay by physicians in charge. Included patients will be followed up until ICU discharge or

drain removal if discharged earlier. Follow-up will then be conducted until hospital discharge, and by phone calls at D28 and D90.

### 2.4 Outcomes

#### *Primary outcome measures*

Primary outcome variable is a composite criteria of major and minor complications related to chest drainage, using a hierarchical sequential approach [22]:

1) composite criterion for major complications: organic lesions (*e.g.* spleen, liver, lung, vessel; calculated frequency 0.2-1.4%) and post-drainage empyema or infection at the site level insertion (calculated frequency 0.2-1.4%) (non-inferiority hypothesis)

And

2) composite criterion on other complications (drain malposition (calculated frequency 0.6-6.5%), drain clogging (calculated frequency of 5.2-8.1%) or drain drop (calculated frequency 1-21%) (superiority hypothesis).

Presented calculated frequencies are based on 2010 BTS guidelines [1].

#### *Secondary outcomes measures*

Drain-ICU trial is intended to determine incidences of drain-related complications that are listed in data collection paragraph below.

### 2.5 Participant timeline

Participant timeline is described in Figure 2.

### 2.6 Methods: assignment of interventions

#### *Allocation and sequence generation*

Randomization will be conducted through a dedicated website, accessible only with a personal password, and protected by SSL (secure socket layer) encryption (Clinsight software, Ennov Clinical, Paris, France), allowing instant and anonymous allocation. Each patient will be assigned a unique identifier and a randomization number. Allocation sequence will be generated using a minimization algorithm stratified on the center, the type of drainage (liquid effusion or pneumothorax), and on presence or absence of invasive mechanical ventilation. Patient's allocation to a group will be conducted by the local investigator who will log into the randomization system using a personal code and entering minimal necessary information.

#### *Blinding*

Since the study is based on two different techniques, masking of participants, care providers and local investigators is impossible. However, data will be analyzed, and statistics performed by a methodologist blinded to allocation groups.

### 2.7 Data collection and management

Study data are prospectively collected and managed by trained research coordinators and/or investigators from each participating center, using Clinsight software (Ennov Clinical, Paris, France).

The following data are collected and registered at ICU admission:

1) General demographic and morphological characteristics, ICU admission reason, medical and surgical histories, ongoing treatments and medications (including those that interact with coagulation), baseline severity score (Simplified Acute Physiologic Score (SAPS)

II and Sequential Organ Failure Assessment (SOFA)), date of mechanical ventilation start (invasive or non-invasive);

2) Drainage indication (pneumothorax or liquid effusion) and location, characteristics of liquid effusion, anticipated volume according to published methods [23-26];
3) General clinical and biological baseline parameters measured in ICU patients including sedation and analgesia parameters (RASS, BPS, BPS-NI, VRS), administered molecules and doses; hemostasis parameters (prothrombin time, activated cephalin time, platelets level); hemodynamic parameters (heart rate, blood pressure); respiratory parameters (clinical signs of acute respiratory failure, respiratory rate, $SpO_2$ (pulsed saturation of oxygen), oxygen flow and delivery interface) and mechanical ventilation parameters (tidal volume, respiratory rate, $FiO_2$ (fraction of inspired oxygen) , inspiratory pressure, positive end-expiratory pressure, plateau pressure, peak pressure, dynamic compliance).

The following data are collected <u>during drainage</u>:

1) General clinical characteristics detailed above, physician status (junior, senior or junior under senior supervision), reported previous experience with drainage techniques and his/her *a priori* choice of technique if the patient was not included in the study, use of ultrasound-tracking and ultrasound-guidance, local or loco-regional anesthesia use, chest drain characteristics (brand, model and size), duration of chest drain insertion and difficulties encountered (acute complications, drainage failure and reason, need for a second operator and/or alternative technique), drained volume and fluid characteristics.
2) Pain and sedation scores are recorded during local anesthesia, drainage and lung re-expansion.
3) Clinical signs suggestive of pulmonary re-expansion oedema will be sought.

4) A drainage site picture once drain in place and secured, but before dressings application, will help to identify whether the drain is in the so-called safety triangle.

Complications, drained volume and fluid characteristics, persistent bubbling, drain manipulations (change of collection case, dressing repair, disconnection, transport of the patient outside the ICU (operative room or CT-scan (Computed tomography scan) facility for example), drain position on control X-rays, drainage site related pain at rest and during mobilization, will be collected daily until drain removal.

At the time of drain removal, ablation criteria, pain, removal and dressing modalities are collected.

ICU and hospital discharge collected data are vital status, ventilatory-free days, length of ICU and hospital stays, persistent pain (DN4 questionnaire, VRS at rest and mobilization).

A phone call at D28 and D90, if patient discharged from the hospital, collects patient's vital status, need for rehospitalization or re-drainage, complications and persistent pain related to chest drainage.

### 2.8 Statistical methods

#### *Sample size estimation*

According to study main objective and hierarchical sequential approach with two primary endpoints set prior to study start, sample size estimation is based on the demonstration of 1) a non-inferiority hypothesis for major complications and 2) a difference between randomized groups for other complications (superiority hypothesis).

For major complications, a rate of 5 to 10% is expected in the control group. Considering a non-inferiority limit of 4%, it is necessary to include 509 patients per group for a unilateral type I error at 5% and a power of 90%.

For other complications, a 15% rate is expected in the control group according to previous work reported in the literature [1]. In order to demonstrate a relative difference between randomized groups of approximately 50%, *i.e.* a difference between 15% and 8%, 450 patients per group are required for a bilateral type I error of 5% and a statistical power greater than 90%.

Finally, it is therefore proposed to include 1020 patients.

### *Statistical analysis*

All statistical analyses will be performed using Stata software (version 13, StataCorp, College Station, USA) prior to unblinding the randomization code, in accordance with recommendations of the International Conference on Harmonization-Good Clinical Practice [27].

Analyses will be performed, firstly, on modified Intent to Treat (mITT) population data and, secondly, on per protocol population. Criteria for inclusion of patients in mITT and per-protocol populations, respectively, are presented below.

Continuous variables will be presented as means and standard deviation (median and quartiles, otherwise) and will be compared using unmatched t-test or Mann-Whitney U-test, as appropriate. Shapiro-Wilk test will be used to assess normality and Fisher-Snedecor test to assess homoscedasticity. Categorical data will be presented in exact numbers and percentages.

A bilateral p-value of less than 0.05 will be considered for statistical significance of all analyses.

### *Statistical analysis: Main Analysis*

The two groups will be compared for the following patients' characteristics at inclusion: compliance with selection criteria, epidemiological and clinical characteristics and treatments. Basic description of patients included in the analysis will be performed, without presenting inferential statistical tests (as recommended).

Protocol violations and protocol violations per patient, as well as reasons for study discontinuation will also be described. The number of patients recruited, and the accumulation curve will be presented for each group.

Main study objective is to compare complication's rates between chest drainage techniques ("Seldinger" and "surgical" methods) in ICU patients requiring pleural drainage, whatever the indication, using a hierarchical sequential approach with two main parameters:

1) With regard to the objective of demonstrating a hypothesis of non-inferiority for major complications, the comparison cannot be made using the usual statistical tests. Moreover, the comparison between both randomization groups will be based on the study of the confidence interval of the absolute difference. This confidence interval approach will be based on EMA (European Medicines Agency) recommendations. Specific tests for the non-inferiority hypothesis, such as Dunnet and Gent tests, will be performed to complete this analysis. If this test is not significant, the use of surgically inserted large-bore drains and small-bore Seldinger drains will not be considered different based on this study. If this criterion is significant, then the question arises as to whether there is at least one additional benefit.

2) Comparison between groups regarding other complications will be made using chi-square or Fisher's exact tests. Next, multiple logistic regression analysis will be used to identify the relevant co-variables in the mITT population associated with main outcome (input criterion for variables will be $p<0.10$), in addition to stratification variables. Then, fitted analyses will be performed using robust Poisson generalized linear mixed model regression, including center, type of drainage (pneumothorax or pleurisy, and in the case of pleurisy, partitioned and viscosity), presence or absence of mechanical ventilation and on-call drainage as random effects. Results will be presented as relative risks and 95% confidence intervals.

These two parameters are set before study beginning. Thus, criteria are considered one after the other in the statistical analysis, sequentially, according to the pre-established hierarchy.
It will be possible to conclude that the effect is shown for all the first statistically significant criteria for the usual threshold (α=5%) up to the first non-significant criterion.

If this trial is not statistically significant, the use of surgically-like inserted large-caliber drains and small-caliber Seldinger drains will not be considered different in this study. If this criterion is statistically significant, the question arises as to whether there is at least one additional benefit. The first second criterion for studying this hypothesis is pre-established in the hierarchy. The hypothesis that the use of surgically inserted large-caliber drains and small-caliber drains (Seldinger) has a first additional benefit is tested with a 5% perfectly controlled type I error. If this test is significant, it can be concluded that the use of surgically inserted large-caliber drains and small-caliber Seldinger drains proved to be of interest (1st test) and that they also provide an additional advantage. No conclusion is possible beyond the first non-significant test.

***Statistical analysis: Secondary Analysis***

Chi-square or Fisher's exact test, as appropriate, will be used for secondary binary results. Multivariate analyses will be performed as described above using a robust Poisson generalized linear mixed model regression.

Continuous parameters will be compared to Student's t-test or Mann-Whitney's test if the assumptions of the t-test are not met. Normality will be studied using Shapiro-Wilk test and homoscedasticity with Fisher-Snedecor test. For multivariate analyses, linear random effects model will be performed with covariates determined according to univariate results and clinical relevance, in addition to the center, type of drainage (pneumothorax or pleurisy (partitioned and viscosity)) and on-call drainage as a random effect. The normality of the residues will be studied as described above. If necessary, a transformation (*e.g*. logarithmic) should be proposed to obtain

the normality of the dependent variable. The results will be expressed as regression coefficients and 95% confidence intervals.

Time-event curves will be calculated using Kaplan-Meier method and will be compared using a logarithmic test in the univariate analysis and a Cox marginal regression in the multivariate analyses. The proportional risk hypothesis will be investigated using Schoenfeld test and graphical representation of residuals, and interactions between possible prognostic factors will also be tested. Results will be expressed as likelihood ratios and 95% confidence intervals.

Repeated measurements (*e.g.* pain levels during and after intervention) will be analyzed using random effects models. The appropriateness of studying a group of fixed effects, evaluation of time points and their interaction taking into account inter- and intra-patient variability, in addition to the center as a random effect will be evaluated.

#### *Method of Accounting for Missing, Unused or Invalid Data*

To put the significant results into perspective, a sensitivity analysis will be conducted to measure the impact of missing data.

In the worst-case scenario, patients with missing data will not respond to any treatment.

Further analyses will then be carried out according to the statistical nature of the missing data (randomly missing or not), in particular multiple imputation or the estimates proposed by Verbeke and Molenberghs, specifically adapted to repeated data.

### 2.9 Methods: monitoring

#### *Data monitoring*

The trial will be overseen by a steering committee regarding the progression and monitoring of the study at Department of Perioperative Medicine, Anesthesia and Critical Care of Clermont-Ferrand University Hospital (France) meetings every 6 months.

Research assistants from the coordinating center will regularly monitor all the centers on site to check adherence to the protocol and the accuracy of the recorded data. After being trained to conduct the protocol and to fulfil the eCRF, an investigator at each center will be responsible for daily patient screening, enrolling patients in the study, ensuring adherence to the protocol and completing the eCRF. Although the individual study assignments of the patients cannot be masked, the coordinating center and all investigators will remain blinded of study group outcomes until database is locked.

### *Harms*

An interim analysis will be performed after the inclusion of 510 patients. The Independent Data and Safety Monitoring Board (DSMB) will recommend that the trial be stopped if it finds a difference between groups in terms of excess mortality (related to one of the two techniques or to an investigating center) or if it finds that continuation of the trial clearly compromises patient safety (in the case of serious adverse events). The Steering Committee will be responsible for the continuation, or discontinuation of the study based on the recommendations of the DSMB.

### *Auditing*

Complications and events related to the chest drainage procedure will be evaluated by an independent adjudication committee.

## 3. DISCUSSION

Chest drainage is a frequent procedure in ICUs worldwide. Two techniques are usually conducted, one using small drains inserted following Seldinger technique and the second using larger drains inserted following surgical-like chest blunt dissection. Those have never been compared in the subset of a large prospective RCT including ICU patients presenting with pneumothorax or pleural effusion. Available recommendations are based on low quality level of evidence studies [1].

We wish to define precisely complications associated with each technique and drainage indication (pneumothorax, type of liquid: thick or not, partitioned...). Expected benefits include improved knowledge on chest drainage in ICU, and its optimization based on the most suitable modality, aiming for better tolerance and efficiency. Without existing consensus, results of the present study might afford insights towards practice changes in a field where complications are potentially severe [28].

Present study may have limitations. First, blinding of individual study assignments will not be possible given characteristics of both strategies under evaluation. A double-blind trial is therefore not possible. Second, participating centers are required to be comfortable with both techniques, otherwise there would be a higher complication rate in the insufficiently mastered technique group. Third, difficulties will arise in studying complications when multiple *ipsi*- and *contra*-lateral drainages occur within the 90-day follow-up period. To compensate for this weakness, any subsequent drainage is required to be with the technique of initial randomization, and an adjudication committee will evaluate complications in regards with the randomized technique.

Drain-ICU trial has several strengths. This large RCT will be the first on the subject and may help to establish strong recommendations on daily clinical practice for chest drainage in ICU with a high level of evidence. Moreover, we have chosen to use a hierarchical sequential

approach for the main judgment criterion which will allow us to conclude by demonstrating effects on several criteria without inflation of type I errors [22, 29]. Drainage technique and not materials used, which is specific to each center, will be studied as a pragmatic reflection of "real life".

Study of secondary judgment criteria will afford insights on drainage conditions and their adequacy with current recommendations. BTS guidelines strongly recommend ultrasound use for pleural effusions' detection and guidance to the safest insertion site (safety triangle). Ultrasound use can also provide information on pleural effusion type. Effusions without internal echoes can be either exudates or transudates, whereas complex effusions are exudates [1, 30]. This technique also allows detection of hemothorax as well as pneumothorax [31].

Ultrasound guidance of drain insertion remains rare and is not recommended in routine practice despite being described elsewhere [32]. Volume of pleural effusion can be anticipated by ultrasound analysis, either in spontaneously breathing or ventilated patients [15, 23-26]. A final theoretical application of ultrasound could be the detection of inappropriate drain position, but remains to be evaluated.

Regardless of the insertion technique or type of pleural effusion, BTS guidelines [1] recommend the insertion of thoracic drains in the axillary region, in the "safety triangle". An anterior approach into the second intercostal space is not recommended in current practice and should be reserved for apical pneumothoraxes. Analysis of pictures systematically taken after drainage, before dressing closure, will allow to locate drain insertion site, and investigate association with possible complications.

Patients often report pain associated with chest drain insertion. Careful local anesthesia with 1% lidocaine, paying particular attention to the skin, periosteum and pleura, as well as protocolized mild sedation are recommended and strongly encouraged by BTS guidelines [1]. This trial will

highlight whether large chest drains are associated with higher pain levels due to progressive chest blunt dissection, and if pain persists in both techniques, even after drain removal.

Finally, BTS guidelines recommend that pleural drainage should not be performed during on-call activity (except in life-threatening emergencies, such as compressive pneumothoraxes) and that all other drainages should be deferred during daytime activity. Drain-ICU trial will afford further information on this point.

In conclusion, Drain-ICU trial is an investigator-initiated pragmatic RCT empowered to test the hypothesis that chest drainage procedures performed using small drains inserted with Seldinger technique may be as efficient as large drain inserted after surgical-like chest blunt dissection without increasing the risk of complications in ICU patients presenting with pneumothoraxes or pleural effusions. These two strategies have never been compared in a large prospective multicenter RCT, and therefore, may help to establish strong recommendations with a high quality of evidence on a daily clinical practice issue: chest drainage of ICU patients.

# 4. DECLARATIONS

## 4.1 Trial status

Patients are expected to be included during a two and a half years inclusion period that began in May 29th, 2020.

2019-2020: Protocol writing (version #1), ethics committee approval (*CPP Tours - Ouest I*); trial tool development (eCRF, randomization system).

May 2020 - November 2022: Patients' inclusions.

2023: Database cleaning and closure. Data analysis, writing of the manuscript and submission for publication.

## 4.2 Ethics approval and consent to participate

Drain-ICU study is an investigator-initiated trial. Study promotion is performed by Clermont-Ferrand University Hospital (France). There is no industrial support nor involvement in the trial. Principal investigators have no financial or other competing interests.

Three methods of consent will be used, as required by current French law [33]. Whenever possible, patients will be included after written informed consent. However, patients may be unable to provide informed consent because of illness severity (*e.g.* altered mental status, use of sedatives). These patients will be included after written informed consent is provided by the next of kin, or using an emergency procedure requiring investigator signature, countersigned by an independent physician, if the next of kin is not present. When available, and as soon as possible after recovery, patients will be retrospectively asked for written consent to continue the trial. Data will be handled in a confidential and anonymous manner, according to French law. Coding subjects will be done by recording the first letter of name and forename, accompanied by a single study identifier indicating the order of subject inclusion, in order to store anonymized data in the eCRF. The sponsor will ensure that each study participant has given his/her consent for access

to his/her personal data that is strictly required for quality control of the study. All original records will be archived at trial sites for 15 years. The clean database file will be anonymized and kept for 15 years.

### 4.3 Availability of data and materials

All investigators will have access to the final data set. Investigators will make available documents and individual data strictly required for monitoring, quality control and audit of the study to persons having access to them, in accordance with the statutory and regulatory provisions in place (articles L.1121–3 and R.5121–13 of the French Public Health Code). Participant-level datasets will be made accessible on a controlled access basis.

### 4.4 Dissemination policy

Findings will be published in peer-reviewed journals and presented at local, national and international meetings and conferences to publicize and explain the research to clinicians, commissioners and service users. Rules of publication will follow the international recommendations according to The Uniform Requirements for Manuscripts [29].

### 4.5 Competing interests

Drain-ICU study is an investigator-initiated trial. Study promotion is performed by Clermont-Ferrand University Hospital (France). There is no industrial support nor involvement in the trial. Principal investigators declare that they have no competing interests.

### 4.6 Funding

No material costs are expected. Equipment used will be those usually available in each investigating center. Other costs (quality control, biostatistician, logistics) will be covered by the research unit of the Perioperative Medicine Department of Clermont-Ferrand University

Hospital. Funders have no influence on study design, conduct and analysis or preparation of this article.

### 4.7 Authors' contributions

BPa, TG and RG, in collaboration with all authors and the Drain-ICU network designed the trial and wrote the manuscript. BPe provided substantial contributions to the conception and design of the study, and wrote the statistical analysis plan and estimated the sample size with TG.

GD, FB, GA, LA, BB, SC, CV, JEB, MJ, BR, RB, LB, NB, AS, DM and EF contributed for drafting work, revising it critically for important intellectual content and approved the final version of the manuscript. All authors give their agreement to be accountable for all aspects of the work and ensure the accuracy and integrity of any part of the work.

### 4.8 Acknowledgements

The following authors and investigators are listed under the name “Drain-ICU network”:
Géraud Galvaing, MD, PhD (Clermont-Ferrand)
Russell Chabanne, MD, MSc (Clermont-Ferrand)
Martin Charvin, MD, MSc (Clermont-Ferrand)
Pierre Couhault, MD (Clermont-Ferrand)
Jérémy Bourenne, MD (Marseille)
Nathanaël Eisenmann, MD (Clermont-Ferrand)

## 5. CONCLUSION

The Drain-ICU trial is a randomized controlled trial designed to test the hypothesis that chest drainage procedures performed with small drains inserted using the Seldinger technique can be as effective as large drains inserted after surgical chest wall dissection, without increasing the risk of complications in resuscitation and intensive care patients with pneumothorax or pleural effusion.

These two strategies have never been compared in a large, multicenter, prospective randomized controlled trial and thus can contribute to establishing sound recommendations with high quality of evidence on a question of daily clinical practice: chest drainage of intensive care unit patients.

L'essai Drain-ICU est une étude randomisée contrôlée destinée à vérifier l'hypothèse selon laquelle les procédures de drainage thoracique réalisées à l'aide de petits drains insérés selon la technique de Seldinger peuvent être aussi efficaces que les gros drains insérés après une dissection chirurgicale de la paroi thoracique, sans augmenter le risque de complications chez les patients de réanimation et de soins intensifs présentant un pneumothorax ou un épanchement pleural.

Ces deux stratégies n'ont jamais été comparées dans une grande étude prospective randomisée contrôlée multicentrique et peuvent donc contribuer à établir des recommandations solides avec une grande qualité de preuves sur une question de pratique clinique quotidienne : le drainage thoracique des patients des unités de soins intensifs.

Clermont-Ferrand, le 2/03/21
Pierre CLAVELOU
Doyen - Directeur

U.F.R. DE MEDECINE Clermont-Ferrand

Clermont-Ferrand, le 26/02/2021
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## 6. FIGURES AND LEGENDS

Figure 1: CONSORT diagram of Drain-ICU trial illustrating randomization and flow of patients in the study.

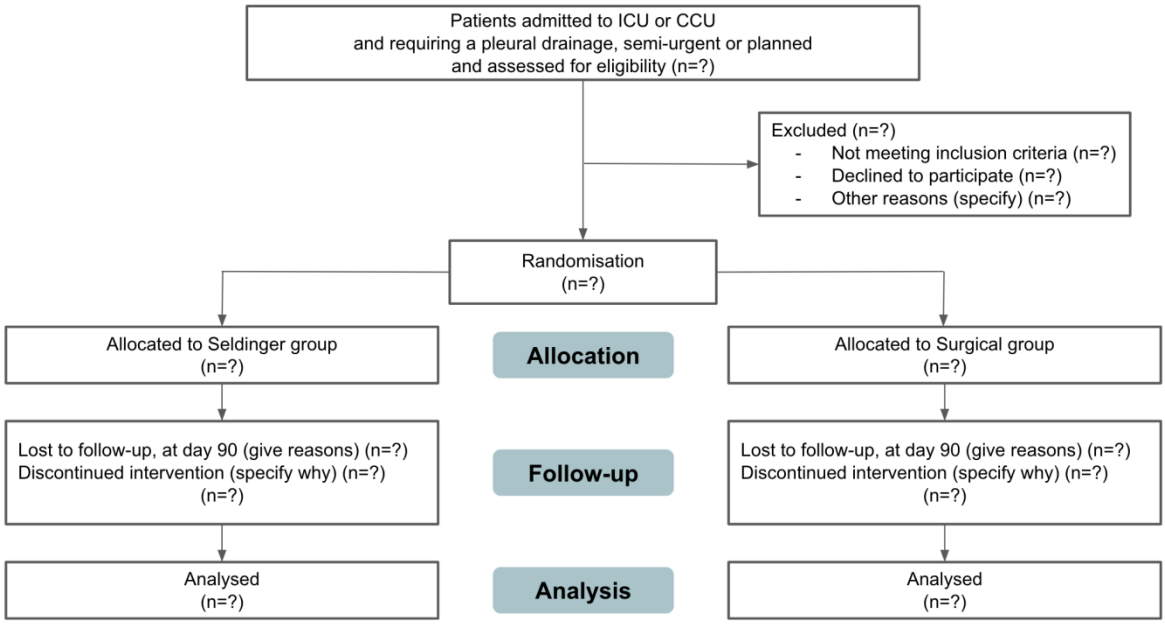


Figure 2: Participant timeline

| | D0 | Daily until chest drain removal | ICU discharge | D28 | D90 |
|---|---|---|---|---|---|
| Informed consent | X | | | | |
| Eligibility | X | | | | |
| Randomization | X | | | | |
| Filing of case report forms | X | X | X | X | X |
| Complication of chest drainage | X | X | X | X | X |
| End of study | | | | | X |

# 7. SUPPLEMENTARY MATERIAL

## 7.1 SPIRIT CheckList

| | | Reporting Item | Page Number |
|---|---|---|---|
| **Administrative information** | | | |
| Title | #1 | Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym | 1 |
| Trial registration | #2a | Trial identifier and registry name. If not yet registered, name of intended registry | 6 |
| Trial registration: data set | #2b | All items from the World Health Organization Trial Registration Data Set | n/a |
| Protocol version | #3 | Date and version identifier | |
| Funding | #4 | Sources and types of financial, material, and other support | |
| Roles and responsibilities: contributorship | #5a | Names, affiliations, and roles of protocol contributors | |
| Roles and responsibilities: sponsor contact information | #5b | Name and contact information for the trial sponsor | n/a |
| Roles and responsibilities: sponsor and funder | #5c | Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities | |
| Roles and responsibilities: committees | #5d | Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee) | |
| **Introduction** | | | |
| Background and rationale | #6a | Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention | 14-16 |
| Background and rationale: choice of comparators | #6b | Explanation for choice of comparators | 14-16 |
| Objectives | #7 | Specific objectives or hypotheses | 16 |
| Trial design | #8 | Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory) | 17 |
| **Methods: Participants, interventions, and outcomes** | | | |
| Study setting | #9 | Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained | 18 |
| Eligibility criteria | #10 | Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists) | 18 |
| Interventions: description | #11a | Interventions for each group with sufficient detail to allow replication, including how and when they will be administered | 18-20 |
| Interventions: | #11b | Criteria for discontinuing or modifying allocated interventions | 19 |

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| modifications | | for a given trial participant (eg, drug dose change in response to harms, participant request, or improving / worsening disease) | |
| Interventions: adherance | #11c | Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return; laboratory tests) | 27, 28 |
| Interventions: concomitant care | #11d | Relevant concomitant care and interventions that are permitted or prohibited during the trial | 18, 19 |
| Outcomes | #12 | Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended | 20 |
| Participant timeline | #13 | Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure) | 20 |
| Sample size | #14 | Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations | 23, 24 |
| Recruitment | #15 | Strategies for achieving adequate participant enrolment to reach target sample size | 18, 28 |
| **Methods: Assignment of interventions (for controlled trials)** | | | |
| Allocation: sequence generation | #16a | Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions | 21 |
| Allocation concealment mechanism | #16b | Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned | 21 |
| Allocation: implementation | #16c | Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions | 21 |
| Blinding (masking) | #17a | Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how | 21 |
| Blinding (masking): emergency unblinding | #17b | If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial | N/A |
| **Methods: Data collection, management, and analysis** | | | |
| Data collection plan | #18a | Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol | 21-22 |
| Data collection plan: retention | #18b | Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols | 27 |
| Data management | #19 | Plans for data entry, coding, security, and storage, including | 27, 28 |

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| | | any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol | |
| Statistics: outcomes | #20a | Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol | 24-26 |
| Statistics: additional analyses | #20b | Methods for any additional analyses (eg, subgroup and adjusted analyses) | 26-27 |
| Statistics: analysis population and missing data | #20c | Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation) | 27 |
| **Methods: Monitoring** | | | |
| Data monitoring: formal committee | #21a | Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed | 28 |
| Data monitoring: interim analysis | #21b | Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial | 28 |
| Harms | #22 | Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct | 28 |
| Auditing | #23 | Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor | 28 |
| **Ethics and dissemination** | | | |
| Research ethics approval | #24 | Plans for seeking research ethics committee / institutional review board (REC / IRB) approval | 32, 33 |
| Protocol amendments | #25 | Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC / IRBs, trial participants, trial registries, journals, regulators) | 32 |
| Consent or assent | #26a | Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32) | 30 |
| Consent or assent: ancillary studies | #26b | Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable | N/A |
| Confidentiality | #27 | How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial | 32, 33 |
| Declaration of interests | #28 | Financial and other competing interests for principal investigators for the overall trial and each study site | 33, 34 |
| Data access | #29 | Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators | 33 |
| Ancillary and post trial care | #30 | Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation | N/A |
| Dissemination policy: trial results | #31a | Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions | 33 |
| Dissemination policy: authorship | #31b | Authorship eligibility guidelines and any intended use of professional writers | 34 |

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| Dissemination policy: reproducible research | #31c | Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code | N/A |
| **Appendices** | | | |
| Informed consent materials | #32 | Model consent form and other related documentation given to participants and authorised surrogates | N/A |
| Biological specimens | #33 | Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable | N/A |

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(Conseil national de l'ordre des médecins)

# SERMENT D'HIPPOCRATE

Au moment d'être admis(e) à exercer la médecine, je promets et je jure d'être fidèle aux lois de l'honneur et de la probité.

Mon premier souci sera de rétablir, de préserver ou de promouvoir la santé dans tous ses éléments, physiques et mentaux, individuels et sociaux.

Je respecterai toutes les personnes, leur autonomie et leur volonté, sans aucune discrimination selon leur état ou leurs convictions. J'interviendrai pour les protéger si elles sont affaiblies, vulnérables ou menacées dans leur intégrité ou leur dignité. Même sous la contrainte, je ne ferai pas usage de mes connaissances contre les lois de l'humanité.

J'informerai les patients des décisions envisagées, de leurs raisons et de leurs conséquences. Je ne tromperai jamais leur confiance et n'exploiterai pas le pouvoir hérité des circonstances pour forcer les consciences.

Je donnerai mes soins à l'indigent et à quiconque me les demandera. Je ne me laisserai pas influencer par la soif du gain ou la recherche de la gloire.

Admis(e) dans l'intimité des personnes, je tairai les secrets qui me seront confiés. Reçu(e) à l'intérieur des maisons, je respecterai les secrets des foyers et ma conduite ne servira pas à corrompre les mœurs.

Je ferai tout pour soulager les souffrances. Je ne prolongerai pas abusivement les agonies. Je ne provoquerai jamais la mort délibérément.

Je préserverai l'indépendance nécessaire à l'accomplissement de ma mission. Je n'entreprendrai rien qui dépasse mes compétences. Je les entretiendrai et les perfectionnerai pour assurer au mieux les services qui me seront demandés.

J'apporterai mon aide à mes confrères ainsi qu'à leurs familles dans l'adversité.

Que les hommes et mes confrères m'accordent leur estime si je suis fidèle à mes promesses ; que je sois déshonoré(e) et méprisé(e) si j'y manque.

Nom, Prénom Signature

# SERMENT D'HIPPOCRATE

En présence des Maîtres de cette FACULTE et de mes chers CONDISCIPLES, je promets et je jure d'être fidèle aux lois de l'Honneur et de la Probité dans l'exercice de la Médecine.

Je donnerai mes soins gratuits à l'indigent et je n'exigerai jamais un salaire au-dessus de mon travail. Admis dans l'intérieur des maisons, mes yeux ne verront pas ce qui s'y passe, ma langue taira les secrets qui me seront confiés et mon état ne servira pas à corrompre les mœurs ni à favoriser le crime.

Respectueux et reconnaissant envers mes MAÎTRES, je rendrai à leurs enfants l'instruction que j'ai reçue de leurs pères.

Que les HOMMES m'accordent leur estime si je suis fidèle à mes promesses. Que je sois couvert d'OPPROBRE et méprisé de mes confrères si j'y manque.

Nom, Prénom Signature

UFR DE MÉDECINE
ET DES PROFESSIONS PARAMÉDICAL
Université Clermont Auvergne

## RESUME DE LA THESE

Le drainage des épanchements pleuraux liquidiens comme gazeux est un geste fréquent dans les unités de réanimation et de surveillance continue. Les indications comprennent les exsudats infectieux, les transsudats, les hémorragies (post-traumatiques ou non), les épanchements pleuraux malins, l'empyème et les pneumothorax. Bien qu'elles soient associées à une faible incidence de complications (allant de 0 à 8 %), certaines de ces dernières peuvent devenir mortelles si elles sont associées à une ponction viscérale par exemple (foie, rate, parenchyme pulmonaire ou cœur). Il a été rapporté dans la littérature que les complications étaient plus importantes en cas de drainage avec des drains de gros diamètre mis en place par technique dite « chirurgicale ». L'utilisation de drains thoraciques de petit diamètre insérés par la technique de Seldinger est plébiscitée par les recommandations britanniques publiées en 2010. Aucune recommandation française n'a été publiée sauf dans le cas particulier des traumatismes thoraciques par la SFAR (Société Française d'Anesthésie-Réanimation) et la SFMU (Société Française de Médecine d'Urgence) en 2015.

Le choix du type de drain thoracique est généralement guidé par l'indication du drainage ou par les habitudes et/ou l'expérience du praticien. Dans le cas d'épanchements pleuraux liquidiens, il pourrait être préférable d'utiliser des drains de petit diamètre, tandis que dans le cas d'épanchements épais comme un empyème ou du sang, il pourrait être préférable d'utiliser des drains de gros diamètre. Cependant, les résultats d'analyses rétrospectives semblent suggérer que l'utilisation de drains thoraciques de petit calibre dans l'une ou l'autre de ces indications est efficace, sans augmentation des taux de complications, comme leur colmatage. Aucun essai randomisé contrôlé n'a, à ce jour, comparé les deux techniques.

L'étude Drain-ICU est un essai thérapeutique randomisé, prospectif, contrôlé, en ouvert, à deux bras parallèles, comparant deux stratégies de drainage thoracique chez 1020 patients de réanimation et de surveillance continue : petits drains insérés selon la technique de Seldinger *versus* gros drains insérés après dissection « chirurgicale » de la paroi thoracique. L'objectif principal est un critère composite de complications majeures et mineures liées au drainage thoracique, selon une approche séquentielle hiérarchique. La taille de l'échantillon permettra de détecter une différence absolue de 4 % entre les groupes, avec un taux d'erreur de type 1 de 5 % et une puissance statistique de 90 %, en présupposant un taux de survenue de 10 % pour les complications majeures (hypothèse de non-infériorité) et de 15 % pour les complications mineures (hypothèse de supériorité).