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GRANT APPLICATION

CANADIAN INTENSIVE CARE FOUNDATION

1. Name of Principal Investigator:
(Last name, first name, initial)

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Co-investigators: (Name in full)

Kevin B Laupland, David Zygun, Rosaleen Chun, Chad Ball, John Kortbeek, Rohan Lall

2. Short Title of the Proposed Research

Management of Occult Pneumothorax Pilot

3. Name and address of institution where the research will be carried out: Same as above ☐x Yes or

4. Give five key words which identify the project:

Occult pneumothorax, pneumothorax, tube thoracostomy, mechanical ventilation, respiratory distress

	NAME: Kirkpatrick AW

5. Summary of the proposal on this page.

The term "Occult pneumothorax" (OPTX), describes a pneumothorax (PTX) that while not suspected on the basis of either clinical examination or plain radiograph, is ultimately detected with thoraco-abdominal computed tomograms (CT)[1-3]. This situation is increasingly common in contemporary trauma care with the increased use of CT. The incidence appears to approximate 5% in injured populations presenting to hospital[4-10], with CT revealing at least twice as many PTXs as suspected on plain radiographs[5,8,10-16]. While PTXs are a common and treatable (through chest drainage) cause of mortality and morbidity, there is clinical equipoise and significant disagreement regarding the appropriate treatment of the OPTX. Based on level III evidence, some authors have recommended observation without chest drainage for all but the largest OPTXs[6-8,14,17], recommendations that contravene the standard dictum for ventilated patients as recommended by the Advanced Trauma Life Support Course of the American College of Surgeons[18]. The controversy is the greatest in the critical care unit population who require positive pressure ventilation. This is also the group for whom the highest rates of chest tube complications have been reported[19]. Complication rates related to chest tubes in general, have been claimed in up to 21% of cases[9,17,19,20].

No previous studies have focused specifically on the population of mechanically ventilated patients. There have been only 45 reported ventilated trauma patients ever randomized to treatment or observation. Enderson found that 8 (53%) of 15 patients had PTX progression with 3 tension pneumothoraces[20]. Brasel found that of 9 observed OPTXs, 2 progressed[9]. Brasel concluded observation was safe[9], while Enderson felt chest tubes were mandatory[20]. We thus propose to carry out a pilot study to examine the need for chest drainage in small to moderate sized OPTX's, as well as the practicalities of carrying out such a study.

The experience and knowledge gained from this pilot will be intended to provide additional support to a future submission to the Canadian Institute for Health Research in order to carry out a multi-centre prospective trial involving the member institutions of the Canadian Trauma Trials Collaborative (CTTC). We believe we have invested more time and effort into developing this line of investigation that any other group in the World. We first reviewed the pertinent literature[1]. We subsequently retrospectively reviewed the outcomes of this entity at both this institution and with collaborators at other CTTC sites[3,21,22]. We have examined the anatomic and practical reasons as to why OPTXs are occult[2,23], as well as novel investigation methods to detect them during the initial evaluation for trauma[16,24-32], and documented the morbidity that may occur with their treatment[33].

6.

	NAME: Kirkpatrick AW

6. Lay Summary of the research proposal. Please use non-scientific, everyday language.

Collapsed lungs are common injuries after traumatic injury that regularly cause needless deaths despite being treatable with chest tubes. Properly used these tubes can be life-saving. Unfortunately, improperly used they can cause pain, bleeding, and other fatal complications themselves. Over the last few decades with increased use of CT scanning it is apparent that many small collapsed lungs are not seen on chest X-rays, and there is little guidance to treating Doctors as to how to treat these patients. There is almost no good data that tells us whether these smaller pneumothoraces require treatment with chest tubes or whether they can simply be closely watched. This proposal is to carry out a simple trial of randomly assigning patients who do not appear to have any symptoms or problems from their occult pneumothorax to either having a standard chest tube or to being watched. Our careful review of the medical literature indicates that we cannot honestly tell patients and their families which treatment is best or required. Our audit of current practice also indicates that Doctors in Calgary and across Canada, regularly prescribe both treatments regularly but in a hap-hazard. The patients in this study will be very closely watched in the intensive care unit and if they develop any breathing problems and do not have a chest tube in, then one will be inserted. The main results that we are trying to determine with this pilot study though, is whether we are able to detect appropriate patients, to recruit them into such a study, and whether the guidelines we have created to manage this patients in this study will be acceptable to all the patients care givers. This data will help us to design a future large multi-centre trial that will hopefully provide information as to how best to manage this type of inured patient.

7. Please provide a clear and concise description as to how the proposed research is relevant to the Mission Statement

We believe that this research is absolutely consistent with the stated mission of improving the care of the critically ill through acquiring knowledge to help the most critically ill. This is a common potentially life-threatening problem, which does not currently have an answer. Traumatic injury remains the leading cause of death for Canadians under 40 years of age, and the leading cause of lost years of productivity, being a disease too often of the young and healthy in the primes of their lives, often with family responsibilities. Further, this condition is typically fully reversible if managed appropriately. It is possible though that we are either hurting our patients by not treating them when they need to be treated, or by injuring them with unnecessary invasive treatments. The only reason we do not have better guidance has been our previous reliance on opinion and dogma, as no one has ever addressed this serious but common question. We would like to rectify this with the support of the Canadian Intensive Care Foundation. Further, we believe that this information will provide benefits to the care of patients all over the world and in ward settings beyond the Intensive Care Unit.

	NAME: **Kirkpatrick AW**

8. Detailed Proposal

(Add no more than 7 additional pages with one inch margins around page – The full proposal document with appendices is available on request)

II. Hypotheses

a. Primary Hypotheses + Outcome Variables: In ventilated patients with small to moderate sized occult PTXs, the rate of respiratory distress will not differ between those treated with tube thoracostomy tubes and those not treated but simply observed.

b. Secondary Hypotheses + Outcome Variables: Observation of small to moderate OPTXs in ventilated patients will not increases the rates of;

i. Emergency chest drainage
ii. Death
iii. Tracheostomy
iv. Acute Respiratory Distress Syndrome (ARDS)
v. Ventilator associated pneumonia (VAP)
vi. Intra-abdominal hypertension (IAH) & the Abdominal Compartment Syndrome (ACS)

Nor increase the lengths of;

vii. Mechanical ventilation
viii. intensive care stay
ix. hospital stay

III. Overview of Study Design: This study will be carried out as the pilot study for a multi-centre randomized single blinded prospective study involving the participating academic critical care units of the Canadian Trauma Trials Collaborative (CTTC) , who care for multisystem trauma patients. Patients 18 years and older without respiratory distress who have PTXs detected on computed tomography (CT) which are not seen on plain radiographs will be screened for eligibility. A log of all eligible patients will be kept and will constitute a measure of incidence data for OPTXs in this setting. Those patients, who do not have respiratory distress, do not already have a drainage catheter in situ, who do not have obvious PTXs on CXR but who have small-moderate sized OPTXs will be considered eligible for the study. Patients will be randomized to either observation or chest tube drainage by the study nurse or an investigator once eligibility has been determined. Randomization will be by prepared randomized opaque concealed envelopes that will be kept in the Critical Care Unit. All the study investigators will be unaware of the contents of these envelopes. This will be done using series of sealed envelopes containing randomly generated numbers. Informed consent to include the patients data in the study analysis will be obtained from the patient or family prior to patient discharge. Standard chest drainage or observation will be performed as per the usual unit procedures. The patient will be expected to be enrolled within six hours of the diagnosis of an OPTX if already undergoing positive-pressure ventilation (PPV), or within 6 hours of commencing PPV if not ventilated at the time of enrollment. All other aspects of the patients care will be as per the usual unit standard as interpreted by the attending critical care attending, including the use of continuous intra-abdominal pressure monitoring[34,35]. Patients will be prospectively followed throughout the critical care unit and hospital stay until discharge and all patients will be followed up by a site investigator 30-60 days after hospital discharge. The primary outcome measure will be episodes of clinical respiratory distress. The secondary outcomes measures will be the need for emergency chest drainage, death, tracheostomy, ARDS, VAPS, IAH, ACS, length of ventilation, length of ICU stay, length of hospital stay.

(See Appendix A: Flow diagram of study)

IV. Patient Selection Criteria

a. Inclusion criteria

1) age >= 18 years
2) small to moderate sized occult pneumothorax identified on chest or abdominal CT scan (Appendix B.)
3) no chest drain in-situ
4) no hemothorax which warrants drainage in the judgment of attending clinician
5) no respiratory compromise in the judgment of the attending clinician

b. Exclusion criteria

1) Not expected to survive
2) Large OPTX (Appendix B.)
3) PTX obvious on plain CXR (not occult)
4) Respiratory distress in the judgment of the attending clinician
5) Pre-existing chest drain in-situ

V. Definitions:

a. Obvious pneumothorax (Obvious PTX) – air in the pleural space, demonstrated by a visible pleural stripe on plain AP supine chest radiograph. Subtle signs of PTX such as the deep sulcus sign, double diaphragm sign, unusually distinct cardiac apex, visualized pericardial fat tags, depressed diaphragms, paramediastinal lucencies, or "crisp" mediastinal silhouettes[36-42]; in the absence of a visible pleural line will NOT be considered obvious.

b. Occult pneumothorax (OPTX) – air in the pleural space documented as present on computed tomography of the chest or abdomen, but without an obvious PTX as defined above.

c. "small" OPTX – no more than 10 mm thick and with a length of < 40 mm (seen on 4 or less contiguous 10 mm CT slices)- (Appendix B).

d. "Moderate" OPTX – thicker than 10 mm with a length or longer than 40 mm (seen on greater than 4 or more contiguous 10 mm CT slices) but not extending posterior to the mid-thoracic coronal line – (Appendix B).

e. "Large" OPTX – thicker than 10 mm or with a length greater than 40 mm (seen on greater than 4 or more contiguous 10 mm CT slices) and extending posterior to the mid-thoracic coronal line (Appendix B).

f. Respiratory distress: acute changes from a "stable" baseline requiring;

- urgent placement of a chest drain
- acute increase by 0.2 in the Fi02
- pharmacologic paralysis for the purpose of improving ventilator synchrony
- hand-bagging
- prone ventilation
- documentation of an adverse respiratory event in the medical record by the attending medical team

g. Intra-abdominal hypertension (IAH) - IAH is defined by either one or both of the following:

1) An IAP $\geq$ 12 mmHg, recorded by a minimum of three standardized measurements conducted 4-6 hours apart.
2) An APP $\leq$ 60 mmHg, recorded by a minimum of two standardized measurements conducted 1-6 hours apart[43].

h. Abdominal Compartment Syndrome (ACS) – ACS is defined as the presence of BOTH[43]:

1) An IAP $\geq$ 20 mmHg with or without APP < 50 mmHg recorded by a minimum of three standardized measurements conducted 1-6 hours apart AND;
2) Single or multiple organ system failure which was not previously present

i. Abdominal Perfusion Pressure (APP) = mean arterial pressure (MAP) - IAP[43].

VI. Informed consent/Ethical Issues: As true clinical equipoise exists, delayed consent to include the patients data in the outcomes analysis will be sought. At the present time, evidence-based medical

review does not allow a determination of the correct therapy for this condition. As such complete clinical equipoise exists. Based on analogy to overt pneumothoraces, it might be assumed that placement of a chest tube is the closest approximation to a "standard of care" that exists. Thus the intervention in this study is the avoidance of an invasive procedure. It is impractical to consider approaching next of kin (if available) to consent for avoiding an invasive procedure for which the indications are essentially unknown. For this reason we would wish to proceed with the trial understanding that the treatment will be randomly allocated, but will be completely "standard" notwithstanding whichever treatment arm is allocated, given that there is no current standard of practice. From this regard, consent will not be required to randomize this treatment, but will be required in order to ethical include the patient in a research analysis. All participating patients will receive the institutional standard of care regarding all other treatments other than chest tube placement. Refusal or withdrawal from the study will not affect any care delivered to the patient.

VII. Stratification and Randomization: Patients will not be stratified in this pilot study. A random number generator will be used to generate sealed opaque envelopes randomly designating patents as receiving or not receiving chest drainage.

VIII. Description of Treatment Groups

a. Chest drainage group: This group will have an intra-pleural catheter placed with the intent of draining the intra-pleural air collection. The size and nature of the catheter, manner of placement, and timing of removal will be at the discretion of the attending clinician.

b. Control group: This group will not have an intra-pleural catheter placed on the basis of the OPTX. Intra-pleural catheters may be placed after enrollment at the attending clinician's discretion. After enrollment this decision will constitute an outcome variable, and will require full documentation as to the indications and rationale.

IX. Baseline and Follow-Up Data Collection

a. Baseline Independent variables

1) Demographic data: age, gender, pre-existing and co-morbid medical conditions including not limited to respiratory, cardiac, endocrine, and neurological diseases will be collected.

2) Admission injury severity data: Mechanism of injury, Injury Severity Score, anatomic injury scores, revised trauma score, Glasgow Coma score, and APACHE II scores, PTX size on CT scan, presence or absence of hemithorax, number of rib fractures, presence or absence of flail chest.

3) Physiologic and laboratory data: mean arterial pressure, heart rate, FIO_2/PaO_2 ratio, mean airway pressure, positive end-expiratory pressure (PEEP) requirements, continuous intra-abdominal pressure, white blood cell count, lactate level, base deficit, and arterial blood gasses.

b. Primary Outcome variable

1) episodes of respiratory distress (see V. Definitions)

c. Secondary dependant variables

1) Respiratory outcomes: requirement for chest drainage, mean airway pressure, FIO_2/PaO_2 ratios, requirement for tracheostomy, days of intra-pleural drainage, confirmed ventilatory associated pneumonia, confirmed acute respiratory distress syndrome, hemothoraces, bacteriologically proven empyema.

2) Global Outcome variables: death, ventilator days, ICU days, hospital days, organ dysfunction and failure, transfusion requirements, IAH, ACS.

X. Statistical Issues: The previous but limited literature on OPTXs in mechanically ventilated trauma patients suggests that there will be a failure of conservative management in 0.42 of the observed patients[20]. In the absence of better data regarding rates of respiratory distress in these patients this can be assumed to represent an event rate. A rate of 0.15 in the treated patients will be assumed. Thus the study will be powered as a trial of equivalence with an event rate difference of 0.25 between studies and controls. In order to detect a difference of 0.25 in the outcome rate, with an alpha of 0.05, and a Power of 90% (B = 0.10), there will need to be approximately 40 in each group. While it is possible that this study might provide this number of patients, the basic goal is to provide further methodological and statistical assistance with the planning of a future multicentre prospective randomized trial.

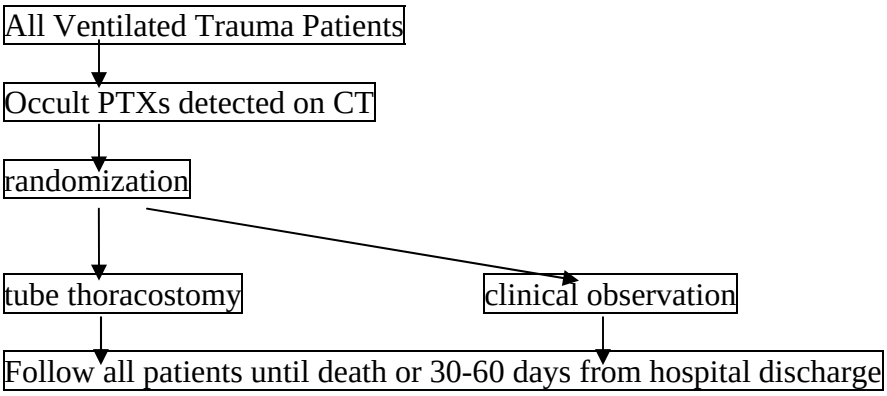
An intent to treat analysis will be used. The primary hypothesis to be tested will be tested with a chi-square

test comparing rates of respiratory distress required in both the control and treatment groups.

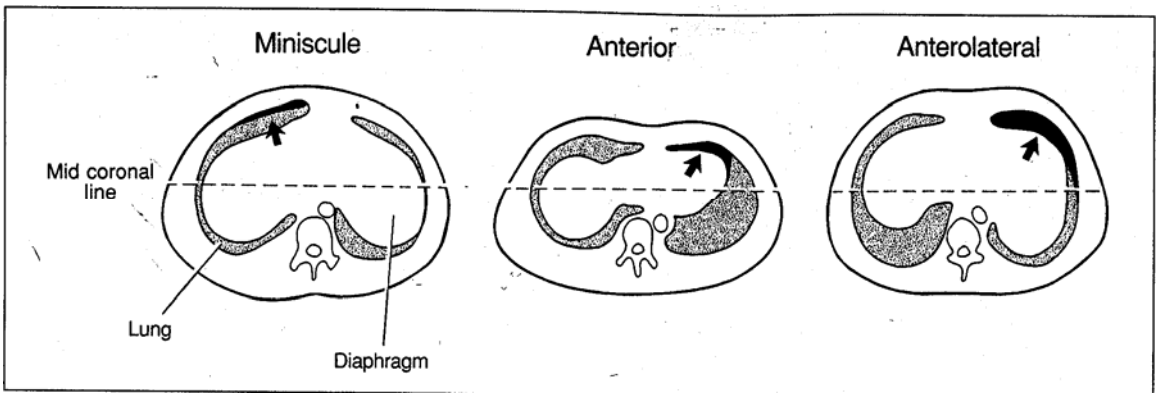
X. **Enrollment Issues: Our previous review of OPTXs over a 12 month period (June 30 2002 – July 1 2003) revealed 57 OPTXs in trauma patients (ISS > 12) entered into the institutional trauma registry. Seventeen of these patients were ventilated[3]. We are now carrying out a prospective surveillance project to detect ALL OPTXs in traumatized patients, including those with an ISS less than 12, who are presumably much more common. Thus, while the recruitment of patients into a study typically much less than the number of eligible patients, we believe there will be a much larger number of eligible patients identified. With this rationale, we would anticipate recruitment of 10 – 20 patients per year at the FMC. While this might allow study completion in 4 years, the intent of this pilot is to test the methodology and practice of this study to allow it to be undertaken in a multicentre fashion by the CTTC**

Appendix A.

Flow Diagram of Study



Appendix B. Classification of Occult Pneumothoraces



CTTC Study Nomenclature

"Small" **"Moderate"** **"Large"**

Modified from Wolfman et al. Validity of CT classification on management of occult pneumothoraces: a prospective study. AJR 1998;171:1317-1323.

	NAME:

9. Ethical and Safety Considerations:

1) Animal Research

Enclose a statement signed by the applicant and the department head that research protocol and the care of the animals conforms to the Guiding Principles for Animal Experimentation as enunciated by the Canadian Council on Animal Care.

□ Form included □ Form to be sent □ X Not applicable

2) Human Research

Enclose a statement signed by the applicant and the department head that the proposed research will be reviewed in a manner which conforms with the guidelines as outlined in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and that the proposed research will not be undertaken until it has been accepted as ethical by such a review.

□ Form included □ X Form to be sent □ Not applicable

3) Biological and Chemical Hazards

Enclose a statement signed by the applicant and the department head that the proposed research will be reviewed in a manner which conforms with the guidelines as outlined in the Health Canada "Laboratory Biosafety Guidelines" and that the proposed research will not be undertaken until it has been accepted as meeting the requirements regarding biological and chemical hazards by such a review.

□ Form included □ Form to be sent □ X Not applicable

Signatures below indicate that the applicant and the institution agree to abide by the above statements and the regulations governing the award. By signing below, the applicant accepts responsibility for all material presented in this applicant and acknowledges having read the Foundations' policies regarding research misconduct.

Applicant's Name Applicant's Signature Date

Department Head's Name Department Head's Signature Date

Institution Name

10. a) Name, title and institution of administrative officer who will administer funds on behalf of the Foundation: Lynn McCrae, Legal Council, Faculty of Medicine, University of Calgary, Calgary, Alberta

b) Is there a possibility that any part of the work may be patentable in the future? □ Yes □ XNo

	NAME: **Kirkpatrick AW**
11. Summary of Funds Requested for 2005/2006:	**Amount Requested:**
a) Salaries	**Research Nurse 0.20 FTE** **$ 15000.00**
b) Equipment	**NA**
c) Experimental Animals	**NA**
d) Materials and Supplies	**NA**
e) Other (specify)	**NA**
f) Travel	**$1000.00**
TOTAL REQUESTED:	**$16000.00**

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