Operative versus Non-operative Treatment of Acute Unstable Chest Wall Injuries: A Multi Centered Randomized Controlled Trial

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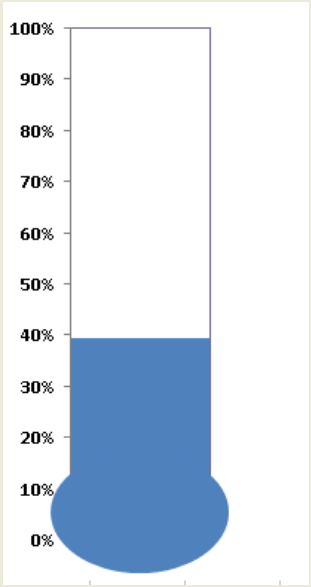
WELCOME

A warm welcome goes out to our newly active sites:

⇒ Dr. Ted Tufescu and Nigar Sultana from Winnipeg, Manitoba
⇒ Dr. Richard A. Malthaner and Deb Lewis from London, Ontario
⇒ Dr. Eduardo Singares-Smith and Diane Lelo from Oak lawn, Illinois
⇒ Dr. Drew Fielder and Adam Clark from Austin, Texas
⇒ Dr. Ed Harvey and Mary Amedeo from Montreal, Quebec

Enrollment status: 39% complete!



Study Update

We now have **12 sites actively recruiting** patients and 3 other centres going through their ethics board. We continue to work with sites going through ethics and/or contracts review. Please contact Lynn if you have been waiting on a contract that has stalled.

Enrollment

We have **81 patients enrolled** at all sites. Our recruitment has increased in the last couple of months with the addition of new sites in US and Canada.

Thank you for all your efforts!

Please screen all rib fractures that present to your site. The screening log should be sent to Jennifer Hidy via email to hidyj@smh.ca or via fax to 416-359-1601 at the end of each month.

Study objectives:

1. To compare early surgical fixation versus conventional, non-surgical treatment of unstable chest injuries on the basis of our primary outcome measure of days spent free from a mechanical ventilator in the first 28 days following injury.
2. To compare other important outcomes between treatment groups including days in ICU, rates of pneumonia and sepsis, need for tracheostomy, mortality, general health outcomes, objective assessment of pulmonary function, and other complications of treatment;
3. To perform a cost-effectiveness analysis comparing the two treatment groups from a health care payer perspective.

Main inclusion criteria:

For inclusion in this study, the patient must be 16-85 years of age and be mechanically ventilated within 3 days of injury. In addition, patients must meet one of the following two indications for surgical fixation of chest wall injury:

1. **Flail chest** *OR*
2. **Severe deformity of the chest wall (Diagnosed by CT scan)**

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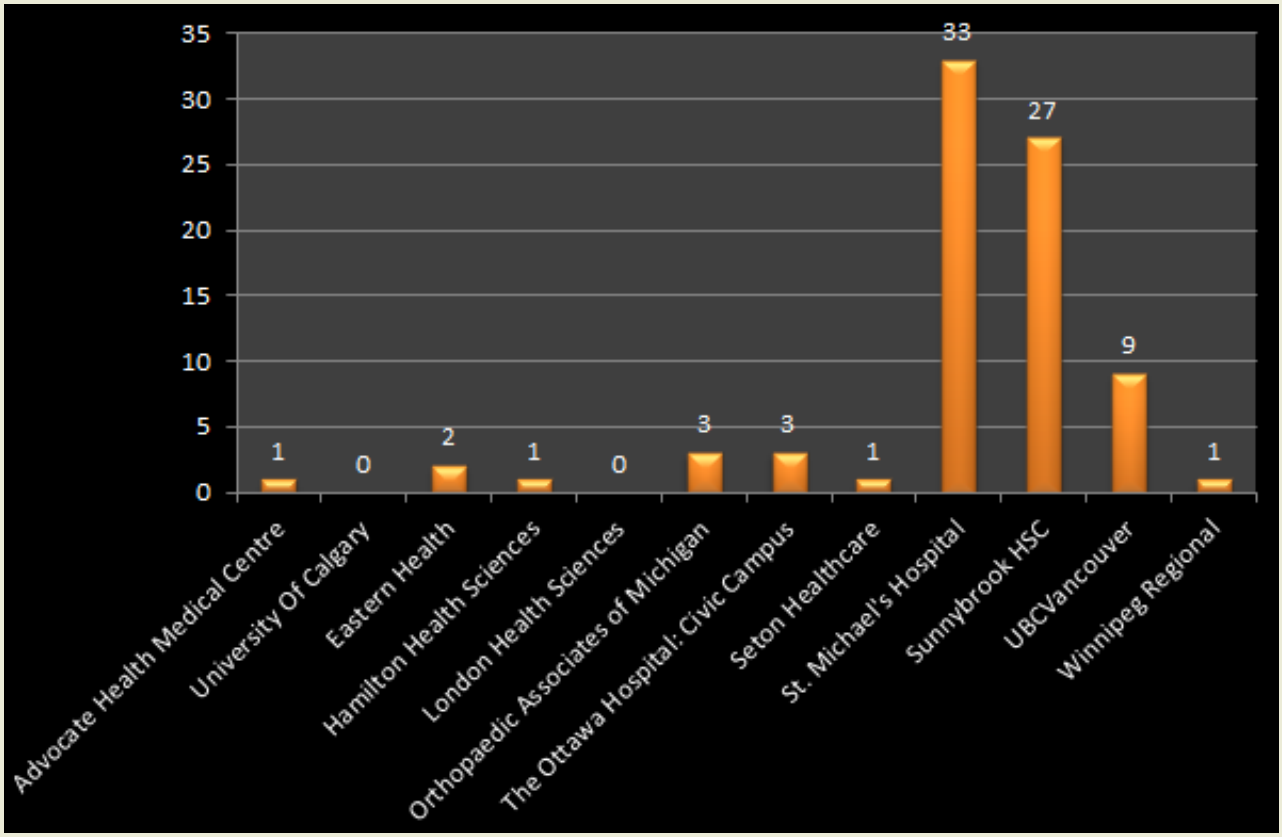
Reminder: Before enrolling patients into the trial, surgeons must meet the following criteria:
A) participate in relevant cadaver labs *OR* **review instructional videos on rib fracture fixation**
AND
B) perform at least 3 rib fracture fixation procedures.
In addition, you must submit to the lead site pre and post-operative x-rays of 3 recent cases of rib fracture fixation performed by you. Dr. McKee will review and provide feedback, and you will then be given randomization instructions.

Enrollment numbers by site



Questions? Comments? Please contact us for all the answers.

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