ISRCTN98682811 https://doi.org/10.1186/ISRCTN98682811

# Trial to re-evaluate ultrasound in the treatment of tibial fractures (TRUST)

| Submission date | Recruitment status |
|---|---|
| 09/09/2005 | No longer recruiting |
| **Registration date** | **Overall study status** |
| 09/09/2005 | Completed |
| **Last Edited** | **Condition category** |
| 06/03/2009 | Injury, Occupational Diseases, Poisoning |

- [ ] Prospectively registered
- [ ] Protocol
- [ ] Statistical analysis plan
- [ ] Results
- [ ] Individual participant data
- [ ] Record updated in last year

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

MCT-67815

# Study information

### Scientific Title
Re-evaluating ultrasound in the treatment of tibial fractures: a randomised controlled trial

### Acronym
TRUST

### Study objectives
That the UltraSound Treatment will significantly reduce the time it takes to return to functionality

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
McMaster University Research Ethics Board approved on the 14th May 2004

### Study design
Randomised controlled trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Tibial shaft fractures

### Interventions
After they agree to participate in the study and have provided informed consent, and as close in time to the reduction and casing as possible, the patients will be randomised to receive either an active or a placebo ultrasound device. In order to ensure a standardised signal, each patient will use a newly calibrated Sonic Accelerated Fracture Healing System (SAFHS 2A) manufactured by Exogen (Piscataway, New Jersey). Smith & Nephew have donated all ultrasound units required for this trial. Neither the patient or the clinician will be able to adjust the ultrasound signal. To ensure reliable positioning of the SAFHS 2A unit during treatment the surgeon will insert a retaining and alignment fixture made of molded plastic into a window centered over the anteromedial surface of the cast at the site of the tibial fracture. This fixture will hold the

treatment head module in place during the daily 20-minute treatment period, thus ensuring that the patient can effectively administer the treatment. After removal of the felt plug and following the application of a small amount of ultrasonic coupling gel (approximately 5 ml) to the surface of the ultrasound head, the patient will position the treatment head module in the window. The main operating unit emits a warning signal if there is not proper coupling to the skin. In addition, the main operating unit contains an integral timer that monitors treatment times and automatically turns the unit off after twenty minutes. A visual and audible signal serves to alert the patient that treatment is complete. The active and placebo devices are identical in every way, in that they have the same visual, tactile, and auditory signals except for the ultrasound signal emitted.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome measure
Physical summary score of the 36-item short form health survey (SF-36)

### Secondary outcome measures
1. Time to radiographic healing of tibial fractures
2. Rates of malunion and non-union of tibial fractures
3. Rates of secondary procedures (operative and non-operative)

### Overall study start date
01/07/2005

### Completion date
31/01/2007

## Eligibility

### Key inclusion criteria
1. Men or women age over 18 years
2. Fracture of the tibial shaft with complete anterioposterior and lateral radiographs
3. Closed or grade I open tibial shaft fracture amenable to non-operative treatment (less than 1.5 cm of shortening, axially stable transverse fractures, spiral oblique of comminuted fractures with less than 12 mm of initial shortening; angulations less than 5° initially; less than 50% displacement)
4. Provision of informed consent

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
50

### Key exclusion criteria
1. State that they cannot comply with the study protocol
2. Have pathological fractures or fractures that are to be treated operatively (comminuted fractures; unstable fracture patterns; tibial shaft shortening greater than 1.5 cm)
3. Likely problems, in the judgment of the investigators, with maintaining follow-up (such as no fixed address, plan to move out of town in the next year)

### Date of first enrolment
01/07/2005

### Date of final enrolment
31/01/2007

## Locations

### Countries of recruitment
Canada

### Study participating centre
**McMaster University**
Hamilton
Canada
L8N 3Z5

## Sponsor information

### Organisation
McMaster University (Canada)

### Sponsor details
1200 Main Street West
Hamilton
Canada
L8N 3Z5

### Sponsor type
University/education

### Website

http://www.mcmaster.ca/

**ROR**
https://ror.org/02fa3aq29

# Funder(s)

**Funder type**
Research organisation

**Funder Name**
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-67815)

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration