

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

<b>Submission date</b> 09/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 09/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 06/03/2009	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Gordon Henry Guyatt

**Contact details**  
McMaster University  
Clinical Epidemiology & Biostatistics  
Health Sciences Centre  
Room 2C12  
1200 Main Street West  
Hamilton  
Canada  
L8N 3Z5  
+1 905 525 9140 ext. 22900  
guyatt@mcmaster.ca

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

## 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 anteroposterior 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 or 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