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

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Physical summary score of the 36-item short form health survey (SF-36)

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration