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Pulsed Ultrasound to Speed-up Healing after Intramedullary nailing of Tibia fractures

Submission date	Recruitment status	[X] Prospectively registered
07/09/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/09/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/09/2008	Injury, Occupational Diseases, Poisoning	[ ] 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
PUSH-IT V1.3 08/08

Study information

Scientific Title

Acronym
PUSH-IT

Study objectives
Adjuvant pulsed ultrasound increases the bony union rate after three months from 20% to 40% after intramedullary nailing of tibia fractures compared to no adjuvant treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board (IRB) of the Charité University Medical Centre (Germany), dated 4th June 2008 (ref: EA1/079/08)

Study design
Pragmatic, randomised controlled multicentre trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Closed or I° open fractures of the tibia

Interventions
Experimental: pulsed, low-energetic ultrasound (Exogen, Smith & Nephew), applied daily for three months
Control: standard of care

The total duration of follow-up is one year after randomisation.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Bony union three months (+/- 1 week) after randomisation, as assessed on plain radiographs by independent, blinded raters.

Key secondary outcome(s))
1. Delayed union and non-union rates
2. Health-related quality of life (36-item Short Form Health Survey [SF-36], EuroQoL instrument [EQ-5D])
3. Functional outcomes (Western Ontario and McMaster Universities Osteoarthritis Index [WOMAC])
4. Duration of sick leave
5. Cost-utility
6. Serious adverse events (SAE)

Secondary outcomes will be assessed after 6 weeks, 3, 6, and 12 months.

Completion date
01/10/2010

Eligibility

Key inclusion criteria
1. Men and women
2. Greater than 18 years old
3. With closed or I° open fractures of the tibia that had been treated by reamed or unreamed locking intramedullary nails less than 10 days prior to randomisation. Patients with fractures of the lateral malleolus, fixed by plates, as well as patients with minor concomitant injuries (bruises, sprains) will be offered trial participation.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Multiple injuries/polytrauma
2. Greater than I° open fractures
3. Pregnant or breastfeeding women
4. Pathological fractures

Date of first enrolment
01/10/2008

Date of final enrolment
01/10/2010

Locations

Countries of recruitment
Germany

Study participating centre

Department of Trauma and Orthopaedic Surgery
Berlin
Germany
12683

Sponsor information

Organisation
German Employer's Liability Insurance for the Administrative Professions (Verwaltungs-Berufsgenossenschaft [VBG]) (Germany)

ROR
https://ror.org/02gaw4292

Funder(s)

Funder type
Government

Funder Name
German Employer's Liability Insurance for the Administrative Professions (Verwaltungs-Berufsgenossenschaft [VBG]) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration