

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

Submission date 07/09/2008	Recruitment status No longer recruiting	☒ Prospectively registered
		☐ Protocol
Registration date 18/09/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 18/09/2008	Condition category Injury, Occupational Diseases, Poisoning	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Julia Seifert, MD PhD

Contact details
Department of Trauma and Orthopaedic Surgery
Unfallkrankenhaus Berlin
Berlin
Germany
12683
julia.seifert@ukb.de

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)

Primary study design

Interventional

Study design

Pragmatic, randomised controlled multicentre trial

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