

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

<b>Submission date</b> 07/09/2008	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/09/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 18/09/2008	<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

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers**  
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

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

### **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 measure**

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

**Secondary outcome measures**

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.

**Overall study start date**

01/10/2008

**Completion date**

01/10/2010

## Eligibility

**Key inclusion criteria**

1. Men and women
2. Greater than 18 years old
3. With closed or 1° 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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

250 (O'Brien-Fleming adaptive design: RD 20%, alpha 0.025, power 83%, 2 x 106 patients, assumed drop-out rate 15%)

**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)

**Sponsor details**

Head Office

Department of Rehabilitation

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**Sponsor type**

Government

**Website**

<http://www.vbg.de/>

ROR

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

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

## **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