ISRCTN13948004 https://doi.org/10.1186/ISRCTN13948004

Effects of low-intensity pulsed ultrasound on tibial transport

Submission date
08/07/2026

Recruitment status
No longer recruiting

Registration date
23/09/2026

Overall study status
Completed

Last Edited
23/09/2026

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Some patients lose part of the tibia after a severe injury or bone infection. One way to rebuild the missing bone is called bone transport. In this treatment, a circular metal frame is attached to the leg and slowly moves a piece of bone across the gap. New bone forms behind it. This method can rebuild large bone defects, but patients often need to wear the frame for many months. Low-intensity pulsed ultrasound, also called LIPUS, is a treatment that sends gentle ultrasound waves through the skin to the bone. It is painless and does not involve surgery. LIPUS has been used to help bone healing in other situations, but it is not clear whether it helps patients who are having tibial bone transport.
The aim of this study was to find out whether adding LIPUS treatment could reduce the time patients needed to wear the circular frame. The study also looked at bone healing on X-rays, patient satisfaction, leg function, treatment adherence, and safety.

Who can participate?
Adults aged 18 years or older could take part if they had a missing section of tibia caused by injury or infection and were being treated with tibial bone transport using a circular external frame.

What does the study involve?
This study took place in two hospitals in Spain. After the first stages of surgical treatment and bone transport had been completed, patients were randomly placed into one of two groups. Patients in the LIPUS group used the EXOGEN® ultrasound device at home for 20 minutes every day. The device was placed on the skin over the area where new bone was forming. Treatment continued until the circular frame was removed. The device automatically recorded how many sessions were completed.
Patients in the control group received the same standard surgical treatment and follow-up but did not receive LIPUS.
The main measurement was the amount of time patients wore the circular frame, adjusted for the size of the bone defect. The study also assessed X-rays, treatment adherence, side effects or device problems, satisfaction, leg function, recurrence of infection, and amputation during follow-up.

What are the possible benefits and risks of participating?
Patients who received LIPUS may have benefited if the treatment helped the new bone mature faster, although this could not be guaranteed. The study may also help improve treatment for future patients with similar complex bone problems.
LIPUS is a non-surgical treatment and was used according to the device instructions. Possible disadvantages included the need to use the device every day, mild local discomfort or skin irritation where the device was applied, or technical problems with the device. All patients continued to receive standard surgical care and follow-up for their condition.

Where is the study run from?
Hospital Universitari Vall d'Hebron, Barcelona, and Hospital Clínico Universitario Virgen de la Arrixaca, Murcia (Spain)

When is the study starting and how long is it expected to run for?
October 2021 to January 2026

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Kushal Mukesh Lakhani Mahtani, kushallakhani@hotmail.com

Contact information

Type(s)
Scientific, Public

Contact name
Dr Kushal Mukesh Lakhani Mahtani

ORCID ID
https://orcid.org/0000-0001-8801-2839

Contact details
Ctra. Gral. del Rosario, 145
Santa Cruz de Tenerife
Spain
38010
+34 (0)922602000
1622253@uab.cat

Type(s)
Principal investigator

Contact name
Dr Pablo S. Corona Pérez-Cardona

ORCID ID
https://orcid.org/0000-0003-4128-3142

Contact details

Pg. de la Vall d'Hebron, 119, Horta-Guinardó
Barcelona
Spain
08035
+34 (0)934893000
pablo.corona@uab.cat

Additional identifiers

Study information

Scientific Title
A multicentre, open-label, parallel-group randomised controlled trial comparing low-intensity pulsed ultrasound versus standard care for reducing the external fixation index in adults undergoing tibial bone transport for post-traumatic or septic segmental tibial defects

Acronym
ELIT

Study objectives
To compare the external fixation index (EFI) between patients undergoing tibial bone transport treated with adjunctive LIPUS technology and a control group and to evaluate final radiological regenerate quality, safety and adherence to LIPUS treatment, and patient satisfaction and functional outcomes between groups.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. Approved 08/10/2021, Research Ethics Committee for Medicines and Research Projects Committee of the Vall d'Hebron University Hospital (Pg. de la Vall d'Hebron, 119, Horta-Guinardó, Barcelona, 08035, Spain; +34 (0)934893000; ceic@vhir.org), ref: PR(ATR)335/2021

2. Approved 08/09/2021, Research Ethics Committee for Medicines (CEIm) Virgen de la Arrixaca Hospital (Ctra. Madrid-Cartagena, Murcia, 30120, Spain; +34 (0)968369500; ceim.arrixaca.sms@carm.es), ref: 2021-10-14-HCUVA

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment

Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Post-traumatic or septic segmental tibial defects treated with bifocal bone transport using circular external fixation

Interventions
Randomisation was performed centrally using REDCap. Participants were allocated in a 1:1 ratio to the LIPUS group or the control group using a computer-generated randomisation sequence with permuted blocks, stratified by participating centre. Allocation was disclosed after completion of the initial reconstructive phases and once the patient was eligible for randomisation. The study was open-label and no sham/placebo device was used.

Patients allocated to the LIPUS group received treatment with the EXOGEN® Ultrasound Bone Healing System. Therapy was initiated after randomization and after specific patient instruction on the use of the device. Thus, LIPUS intervention was focused on the bone regenerate maturation phase once the initial reconstructive phases of surgical treatment had been completed.

Treatment consisted of a daily 20-minute application, performed at home, with the transducer placed on the skin over the bone regenerate and using coupling gel to facilitate transmission of the ultrasound signal.

LIPUS therapy was continued until definitive removal of the circular external fixator. Actual treatment exposure was quantified using the internal log of the EXOGEN® device, which automatically records completed sessions. Treatment adherence was expressed as the percentage of completed sessions relative to the total number of prescribed sessions during the treatment period. Adequate adherence was defined as completion of at least 95% of the prescribed sessions.

Participants in the control group received the same standard surgical and follow-up protocol for tibial bone transport using circular external fixation, but without adjunctive LIPUS treatment.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
EXOGEN® Ultrasound Bone Healing System

Primary outcome(s)
1. External Fixation Index (EFI) (months/cm) measured using the total duration of circular external fixation in bone transport configuration, expressed in months, divided by the length of the segmental tibial bone defect, expressed in centimetres, at the definitive removal of the

circular external fixator, using the period from circular external fixator application to definitive external fixator removal

Key secondary outcome(s)
1. Radiological quality of the bone regenerate measured using plain radiographs classified according to the Li et al. radiological classification. Regenerate morphology and Li type are recorded, and the regenerate is categorised as favourable or non-favourable according to predefined radiological criteria at the definitive removal of the circular external fixator

2. Adherence to LIPUS treatment measured using the internal log of the EXOGEN® Ultrasound Bone Healing System, which automatically records completed treatment sessions. Adherence is expressed as the percentage of completed sessions relative to the total number of prescribed sessions. Adequate adherence is defined as completion of at least 95% of prescribed sessions. Measured at throughout the LIPUS treatment period, from treatment initiation after randomisation until definitive removal of the circular external fixator or until discontinuation of LIPUS exposure.

3. Safety of LIPUS treatment measured using adverse events, local complications, and technical incidents attributable to the EXOGEN® Ultrasound Bone Healing System, at throughout the LIPUS treatment period, from treatment initiation after randomisation until definitive removal of the circular external fixator or until discontinuation of LIPUS exposure

4. Patient satisfaction measured using the Self-Administered Patient Satisfaction Scale (SAPS), recorded as ordinal satisfaction categories, at the first outpatient consultation after definitive removal of the circular external fixator

5. Lower limb function measured using the Lower Extremity Functional Scale (LEFS) at 12 months after definitive removal of the circular external fixator

6. ASAMI functional result measured using the functional classification of the Association for the Study and Application of the Method of Ilizarov (ASAMI), recorded as ordinal categories, at 12 months after definitive removal of the circular external fixator

7. ASAMI bone result measured using the bone classification of the Association for the Study and Application of the Method of Ilizarov (ASAMI), recorded as ordinal categories, at 12 months after definitive removal of the circular external fixator

8. Infection recurrence measured using clinical follow-up, recorded as presence or absence of infection recurrence, at during the 12 months following definitive removal of the circular external fixator

9. Amputation measured using occurrence or non-occurrence of limb amputation at during the 12 months following definitive removal of the circular external fixator

Completion date
30/01/2026

Eligibility

Key inclusion criteria

1. Age: 18 years old and older
2. Affected bone segment: tibia
3. Aetiology of the segmental bone defect: post-traumatic or infectious septic nonunion
4. Selected treatment: bone transport using circular external fixation according to the treatment protocol of the Osteoarticular Septic Surgery Unit (UCSO) at Vall d'Hebron University Hospital (HUVH)
5. Type of bone transport: bifocal, with a single osteotomy
6. Patients who freely and without coercion agree to participate in this clinical trial, and who have sufficient autonomy and capacity to read and understand the patient information sheet and sign the informed consent form for participation

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
120 Years

Sex
All

Total final enrolment
26

Key exclusion criteria
1. Paediatric patients
2. Bone defects of oncological aetiology
3. Bone transport procedures performed using monolateral external fixation
4. Trifocal bone transport procedures, involving double osteotomy
5. Relative contraindications and warnings for use of the EXOGEN® Ultrasound Bone Healing System

Date of first enrolment
21/10/2021

Date of final enrolment
12/02/2024

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Universitari Vall d'Hebron
Pg. de la Vall d'Hebron, 119, Horta-Guinardó
Barcelona
Spain
08035

Study participating centre
Hospital Clínico Universitario Virgen de la Arrixaca
Ctra. Madrid-Cartagena
Murcia
Spain
30120

Sponsor information

Organisation
Vall d'Hebron Institut de Recerca

ROR
https://ror.org/01d5vx451

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Individual participant data will not be made publicly available because of the small sample size, the rarity and complexity of the condition, and the potential risk of participant re-identification. Anonymised aggregate data will be reported in the doctoral thesis and any resulting publications. Reasonable requests for additional anonymised data may be considered by the study investigators, subject to sponsor approval and applicable ethics and data protection requirements.

IPD sharing plan summary

Other