ISRCTN16465304 https://doi.org/10.1186/ISRCTN16465304

Can we improve healing in broken shin bones by changing the settings on the surgical frame that is normally used to fix these injuries?

Submission date
06/04/2021

Recruitment status
No longer recruiting

Registration date
21/05/2021

Overall study status
Completed

Last Edited
21/04/2022

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
This study is comparing two methods of fixing broken shin bones. Commonly doctors treat broken shin bones by attaching a frame to the outside of the leg which goes into the bone. This frame is fixed firmly in place, ensuring the broken bone cannot move as it heals. Recent research in animals suggests that better results could be achieved if the frame is kept slightly loose for the first few weeks, allowing for the bone to heal more before it is set firmly in place. This method has been used in humans safely, but so far no one has measured whether it is better or worse than the current treatment.

Who can participate
Adults (aged 18 or above) with broken shin bones

What does the study involve?
Patients who agree to take part in the trial will receive either the normal rigid frame, or a frame that is fixed marginally looser initially. Those with the more loose frame will have an x-ray after 2-3 weeks, and at that point they will have their frame tightened. Apart from this, all the patients will receive the normal level of care. Both frames should still allow the patients to walk on the leg as their pain eases. Patients will be seen regularly up until at least 1 year after your injury to see how they are getting on. They will also be asked to complete questionnaires about their experience.

What are the possible benefits and risks of participating?
This study will inform which treatment is the best for people with this potentially life-changing fracture. Participants will not benefit from this study but their contribution will help develop and guide the future treatment. The risks of receiving either treatment are the standard risks of receiving the surgery. The surgeon will be able to discuss the risks of the procedure in depth. The standard risks for any tibial fractures are pain, infection (<3%), delayed/non union (< 5%), malunion (<5%). Other risks from having surgery are blood clots, and damage to adjacent structures such as blood vessels, nerves or tendons. Some of these can cause serious or long-lasting problems.

Where is the study run from?
Hull University Teaching Hospitals (UK)

When is the study running and how long is it expected to run for?
March 2020 to April 2024

Who is funding the study
Investigator initiated and funded

Who is the main contact?
Mr Hemant Kumar Sharma, h.sharma@hull.ac.uk
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
289401

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 289401

Study information

Scientific Title
Assessment of bone healing time in tibial fractures; Static vs variable dynamization external fixation

Acronym
B-VAST

Study objectives
Variable reverse dynamization external fixation for the treatment of tibial fractures will result in improved fracture healing times compared to the standard method of static external fixation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/04/2021, London - Queen Square Research Ethics Committee (HRA NRES Centre Bristol
3rd floor, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8061; queensquare.rec@hra.nhs.uk), REC ref: 21/LO/0181

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Adult patients with tibial fractures

Interventions
Patients will be randomly allocated to receive either the intervention (variable reverse dynamization external fixation) or the control (standard static external fixation). This randomisation will be done via computer software, the trial will not be blinded.

Both treatments arms receive the same operation to fix the tibial fracture with an external fixator frame (which is standard practice). The difference between the two treatments is that in the reverse dynamisation group, the frame settings will be different (initially slightly looser, to allow small movements at the fracture site and encourage bone healing). Both groups of patients will still be able to mobilise as pain allows, no cast is required.

At 2 - 3 weeks the patients in the reverse dynamization group will have an extra x-ray to show whether the bone has started to heal, at this point the frame settings will be altered to become rigid like in the other group. All other intervention in the trial will be standard care such as routine follow up, x-rays, and physiotherapy.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Time to bone healing, measured using the Radiographic union (RUST) score at 3, 6, 12 weeks and every following 6 weeks until radiographically united (RUST score 9 or above)

Key secondary outcome(s))
1. Ankle function according to patient measured using Olerud and Molander Ankle score at baseline, 3, 6 and 12 months after frame removal
2. Health-related quality of life measured using EuroQol 5 Dimensions score at baseline, 3, 6 and 12 months after frame removal
3. Knee function according to patient measured using Oxford knee score at baseline, 3, 6 and 12 months after frame removal
4. Complications measured using case report forms and hospital records at 3, 6 and 12 months
5. Resource use and work impact measured using questionnaires and hospital records at 3, 6 and 12 months

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Patients 16 years or older
2. Isolated unilateral or bilateral 41A & B, 42A B&C and 43 A tibial fractures
3. Traverse fractures, short oblique, and fractures with single butterfly
4. Where the treating surgeon believes the patients will benefit from surgical stabilisation

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. More the 28 days since fracture
2. Polytrauma - closed head injury, spinal fractures, pelvis/acetabular fractures, floating knee, femoral fractures, foot/ankle fractures or dislocations, knee dislocation or ligamentous injuries
3. Comminuted and segmental fractures
4. Previous failed fixation
5. Pathologic fracture
6. Patient is/would be unable to understand instructions for treatment
7. Patient declines consent to participate
8. Pregnant

Date of first enrolment

30/05/2021

Date of final enrolment
30/04/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Hull Royal Infirmary
Hull University Teaching Hospitals
Trauma and Orthopaedic department
Analby road
Hull
United Kingdom
HU3 2JZ

Study participating centre
James Cook University Hospital
Trauma & Orthopaedic department
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Northern General Hospital
Trauma & Orthopaedic department
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Leeds General Infirmary
Trauma & Orthopaedic department
Great George street

Leeds
United Kingdom
LS1 3EX

Sponsor information

Organisation
Hull University Teaching Hospitals NHS Trust

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version V4	14/03/2021	21/05/2021	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version V3	14/03/2021	21/05/2021	No	No