# 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	Recruitment status No longer recruiting	[X] Prospectively registered		
Desistration data		[X] Protocol [] Statistical analysis plan		
21/05/2021	Completed	Results		
Last Edited 21/04/2022	<b>Condition category</b> Musculoskeletal Diseases	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 Matthew Marples, Matthew.marples@nhs.net

# **Contact information**

**Type(s)** Scientific

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# Additional identifiers

EudraCT/CTIS number Nil known

**IRAS number** 289401

**ClinicalTrials.gov number** Nil known

Secondary identifying numbers 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

#### Secondary study design Randomised controlled trial

**Study setting(s)** Hospital

**Study type(s)** Treatment

**Participant information sheet** See additional files

# 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 measure

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)

# Secondary outcome measures

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

Complications measured using case report forms and hospital records at 3, 6 and 12 months
Resource use and work impact measured using questionnaires and hospital records at 3, 6 and
months

# Overall study start date

20/03/2020

# **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

**Age group** Adult

**Sex** Both

**Target number of participants** 30

# 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

England

United Kingdom

#### 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

Sponsor details R&D Department Daisy Building Castle Hill Hospital Hull England United Kingdom HU16 5JQ +44 (0)1482875875 James.Illingworth@hey.nhs.uk

**Sponsor type** Hospital/treatment centre

# Funder(s)

**Funder type** Other

**Funder Name** Investigator initiated and funded

# **Results and Publications**

# Publication and dissemination plan

The results of the study will be presented at national and international surgical meetings and published in peer-reviewed medical and orthopaedic journals.

# Intention to publish date

31/12/2024

# 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?
Participant information sheet	version V4	14/03/2021	21/05/2021	No	Yes
Protocol file	version V3	14/03/2021	21/05/2021	No	No
HRA research summary			28/06/2023	No	No