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Segmental tibial fracture fixation - a feasibility study

Submission date
02/05/2019

Recruitment status
No longer recruiting

Registration date
10/05/2019

Overall study status
Completed

Last Edited
13/04/2021

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Every year, many people break their legs. In 12%, the tibia (shin bone) fractures into several pieces that sometimes poke out through the skin requiring a difficult operation. There are two main ways to carry out the operation, either putting a metal rod in the bone or a metal frame outside the bone to help it heal. It is not known which operation is better as previous research looking at these treatments has not been done well and has not provided any definite answers. The researchers are planning a study across the NHS to compare treatment with a metal rod to a frame to see which is better. Before doing a large study like this they need to consider how best to run it and if it will work in practice. They need to know if patients and surgeons would be willing to take part, how they feel about the two different operations and how they should measure "success" after the operation. This is called a feasibility study and the aim is to find out whether a larger study is possible and how it should be run.

Who can participate?
Patients aged 16 and over with a tibia (shin) that is fractured in two or more places and that needs to be repaired with either a metal rod or frame.

What does the study involve?
Participants are randomly allocated to be treated with one of the operations below:
A – Intramedullary Nail
In this operation the surgeon inserts a metal rod into the middle of the tibia, from the knee to just above the ankle. There is no metal visible outside the skin. The metal rod stays within the bone after the patient has recovered.
B – Circular Frame External Fixation
In this operation the surgeon builds a metal frame around the leg, which is connected to the bone with pins. The frame stays in place until the bone has healed. It needs to be cleaned and looked after during this time. When the bone is healed there is another operation to remove the frame. After this there is no metal left in the leg.
After the operation, the clinical team looks after study participants with no change to usual care. 3 and 6 months later, the research team in Oxford send participants short questionnaires. These take around 15 minutes to fill out and ask about the patients' health and recovery since their operation.

What are the possible benefits and risks of participating?
The researchers cannot guarantee a benefit to patients who take part in this study. The results from the study may benefit future patients with similar fractures. Taking part in the study will not change the standard of care participants receive. Both operations are already routinely done in the NHS.

Where is the study run from?
St George's University Hospitals NHS Foundation Trust is the study sponsor, meaning they are responsible for the study. The Surgical Intervention Trials Unit in Oxford and the Oxford Clinical Trials and Research Unit are supporting the study management.

When is the study starting and how long is it expected to run for?
October 2018 to May 2020

Who is funding the study?
National Institute for Health Research (NIHR), Research for Patient Benefit (RfPB) programme (UK)

Who is the main contact?
Miss Caroline Hing
stiff@ndorms.ox.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Molly Glaze

Contact details
Surgical Intervention Trials Unit (SITU)
Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences
University of Oxford
Botnar Research Centre
Windmill Road
Oxford
United Kingdom
OX3 7LD
+44 (0)1865 223489
stiff@ndorms.ox.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
246299

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
40851; 2018.0277, IRAS 246299

Study information

Scientific Title
Segmental Tibial Fractures, reamed Intramedullary nailing versus circular Frame external Fixation - a feasibility study

Acronym
STIFF-F

Study objectives
Every year, many people break their legs. In 12%, the tibia (shin bone) fractures into several pieces that sometimes poke out through the skin requiring a difficult operation. There are two main ways to carry out the operation, either putting a metal rod in the bone or a metal frame outside the bone to help it heal. It is not known which operation is better as previous research looking at these treatments has not been done well and has not provided any definite answers.

The researchers are planning a study across the NHS to compare treatment with a metal rod to a frame to see which is better. Before doing a large study like this they need to consider how best to run it and if it will work in practice. They need to know if patients and surgeons would be willing to take part, how they feel about the two different operations and how they should measure “success” after the operation. This is called a feasibility study and will show whether a larger study is possible and how it should be run to give us an answer.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 30/04/2019, South Central – Berkshire Research Ethics Committee (Bristol REC Centre, Whitefriars, Level 3 Block B, Lewins Mead, Bristol, BS1 2NT; Tel: +44 (0)207 104 8241; Email: nrescommittee.southcentral-berkshire@nhs.net), ref: 19/SC/0073

Study design
Feasibility study consisting of randomised pilot, patients and staff qualitative study, rehabilitation survey

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Segmental tibial fractures

Interventions
Participants will be assigned to receive an intramedullary nail or a circular frame external fixation. A web-based randomisation system will be used and the allocations will be computer generated with a 1:1 ratio, and stratified by site using random permuted blocks of varying size within stratum.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The feasibility of a multicentre randomised controlled trial comparing intramedullary nailing (IN) with circular frame external fixation (CFEF), measured through the rates of recruitment and retention in a randomised pilot study over the 21-month study period.

Key secondary outcome(s))
1. Conflicts or areas of concern for the research pathway compared with the existing clinical pathway, measured through the identification of all adults with segmental tibial fractures, recording the rationale for eligibility and the reasons why eligible patients do not enter the study. Interviews with patients and staff will explore this further. This will be measured over the 21 month study period
2. Compliance with the randomised allocation, measured by the completion of allocated surgical procedure over the 6-month recruitment period.
3. Standard deviation of the outcome measure Disability Rating Index to estimate the definitive sample size. This will be measured using the Disability Rating Index 6 months after randomisation
4. Feasibility of a definitive economic evaluation of IN versus CFEF, measured using Health Resource Use information 6 months after randomisation
5. Quality of life post-fixation, measured using Pittsburgh Sleep Quality Index, Tampa Scale of Kinesiophobia and EQ-5D-5L 6 months after randomisation
6. Healing rates, measured by radiological images assessed by the RUST score 6 months after randomisation
7. Current post-operative rehabilitation regimes, measured through a rehabilitation survey sent to healthcare professionals, and through interviews with staff and patients to identify current experience of rehabilitation. This will be measured over the 21 month study period
8. The variability of patient experiences of injury, treatment and recovery, such as pain, mobility, emotions and body image, across the two treatment options. This will be measured using interviews with patients to gain a detailed understanding of the impact of both treatments and outcomes important to them. This will be measured over the 21 month study period
9. The views of clinicians and patients on the factors that facilitate or inhibit trial recruitment, measured using interviews with staff and patients/consultee to identify the feasibility of undertaking a full trial. This will be measured over the 21-month study period

Completion date
04/05/2020

Eligibility

Key inclusion criteria
Adults (16 years and over) with a segmental tibial fracture (open or closed) deemed suitable for either an intramedullary nail or an external fixation

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
3

Key exclusion criteria
1. Patients under 16
2. Prior failed fixation
3. Pathological fracture
4. Infection present
5. Pre-existing (pre-injury) skin condition which precludes open surgery
6. Patient is/would be unable to understand instructions for treatment*
7. Patient is unable to complete the follow-up requirements
8. More than 21 days since injury

Date of first enrolment
13/05/2019

Date of final enrolment
06/02/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St George's Hospital
Blackshaw Road
London
United Kingdom
SQ17 0QT

Study participating centre
St Mary's Hospital
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Royal Liverpool University Hospital
Prescot Stree
Liverpool
United Kingdom
L7 8XP

Sponsor information

Organisation
St George's University Hospitals NHS Foundation Trust

ROR
https://ror.org/039zedc16

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/04/2021	13/04/2021	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes