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Trial of acute femoral fracture fixation

Submission date
26/05/2016

Recruitment status
No longer recruiting

Registration date
26/05/2016

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
The knee is the largest weight-bearing joint in the body, where the shin bone (tibia) and thigh bone (femur) meet. As people age bones naturally weaken, and so the elderly are particularly vulnerable to knee pain and injury. Every year, many older adults in the UK suffer from distal femur fractures (a fracture at the end of the thigh bone, just above the knee joint). In most cases, the main treatment offered is surgical fixation. This is an operation in which the broken pieces of bone are lined up, and held in place with wires, screws or metal plates. This study will be looking at two common surgical fixation operations for patients with distal femur fractures: 'locking plate fixation' where a plate is screwed to the surface of the bone, and 'nail fixation' where a rod is inserted into the centre of the bone. The aim of this study is to find out whether a larger scale study comparing the effectiveness of these two techniques would be feasible

Who can participate?
Adults with a fractured femur which the attending surgeon feels would benefit from surgery to fix the fracture.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo the 'locking plate fixation' procedure, in which a plate is screwed to the surface of the bone on either side of the break. Those in the second group undergo the 'nail fixation' procedure, in which a rod is inserted into the centre of the bone on either side of the break to hold the broken pieces together. Participants in both groups are followed up six weeks and four months later in order to determine how effective the treatment has been in terms of quality of life and disability. The amount of participants who were able to be recruited to the trial and the costs of conducting the trial are also recorded in order to find out whether a larger scale trial would be possible.

What are the possible benefits and risks of participating?
As with any major operation, surgery carries some risks of bleeding, blood clots, damage to nerves and blood vessels, and risks associated with anaesthetic. These risks are similar for both treatment options and are the same if patients choose not to participate in this research. There are no specific benefits to taking part in this trial. However, the information that we get from this trial should help us with the development of the bigger trial, which we hope will ultimately provide an answer about the most suitable treatment for this type of injury.

Where is the study run from?
Seven NHS Trusts in England (UK)

When is the study starting and how long is it expected to run for?
July 2015 to December 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Robin Lerner
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
TrAFFix

Study information

Scientific Title
For patients with an acute fragility fracture of the distal femur, is there a clinical and cost-effectiveness difference between locking plate fixation and retrograde intramedullary nail fixation?

Acronym

TrAFFix

Study objectives
The aim of this study is to investigate the feasibility of running a large definitive study comparing the effectiveness of two common operations for patients with distal femur fracture (locking plate fixation and nail fixation).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 5, 01/08/2016 , ref: 16/WA/0225

Study design
Multi-centre feasibility randomised parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Quality of life

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
Fragility fractures of the distal femur

Interventions
Randomisation will be via a web based secure randomisation service, and will take into account the hospital and cognitive status of the patient. This will make sure that around the same number of patients with cognitive impairment are randomised to each arm, and that each hospital treats around the same number of patients in each arm. Participants will undergo surgery at the next available opportunity on a planned trauma list. Exact surgical procedures, including X-rays and imaging, will be as per local guidelines. Following fixation all patients will undergo a routine rehabilitation programme prior to discharge from hospital.

Patients will be randomised to fracture fixation with either a locking plate or intramedullary nail:

Locking plate fixation: Fixation of the fracture will be achieved with anatomical distal femoral locking-plate and screws. Locking plates will be defined as those in which at least one fixed angle locking screw is placed distal to the fracture. The operating surgeon will determine the

length, number and type of additional screws. The details of surgical incision and approach, fracture reduction, number and type of other screws and supplementary fixation with wires or screws will be at the surgeon’s discretion as per their normal clinical practice.

Intramedullary nail fixation: Fixation of the fracture will be achieved with a proximally and distally locked nail that spans the entire diaphysis of the femur. All nails will be introduced retrograde through the knee joint. The details of surgical incision and approach, fracture reduction, number and type of other screws and supplementary fixation with wires or screws will be at the surgeon’s discretion as per their normal clinical practice.

Follow-up will be at 6 weeks and 4 months after the injury when the questionnaires will be completed again.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Recruitment rate, calculated throughout the study and determined as the number of eligible participants who gave consent to participate
2. Completion rate of the EQ-5D-5L is measured 4 months post injury

Secondary outcome measures
1. Demential Quality of Life questionnaire (DEMQoL) at baseline, 6-weeks post injury, and 4-months post-injury
2. Disability rating index (DRI) at baseline, 6-weeks post injury, and 4-months post-injury
3. Mixed methods analysis of a process evaluation, including patient and staff interviews throughout the length of the trial

Overall study start date
14/07/2015

Completion date
28/02/2018

Eligibility

Key inclusion criteria
1. Patients of 18 years old and above
2. Present to participating hospitals with a fracture of the distal femur (i.e. involving the distal 2 "Muller" squares)
3. Attending surgeon feels that the patient will benefit from internal fixation of the fracture

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
52

Total final enrolment
23

Key exclusion criteria
1. Patients who have a knee or hip arthroplasty that requires revision
2. A pre-existing arthroplasty that precludes fixation with an intramedullary nail
3. Patients with pre-existing femoral deformity will also be excluded

Date of first enrolment
14/10/2016

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Berkshire NHS Foundation Trust
Royal Berkshire Hospital
London Road
Reading
United Kingdom
RG15AN

Study participating centre
Oxford Radcliffe Hospitals NHS Trust
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre

Leeds Teaching Hospitals NHS Trust
St James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Nottingham University Hospitals NHS Trust
Queen's Medical Centre
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Portsmouth Hospitals NHS Trust
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
University Hospitals of Leicester NHS Trust
Gwendolen House
Gwendolen Road
Leicester
United Kingdom
LE5 4QF

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Stoke-on-Trent
United Kingdom
ST4 6QG

Sponsor information

Organisation
University of Oxford

Sponsor details
Joint Research Office
Block 60
Churchill Hospital
Old Road
Headington
Oxford
England
United Kingdom
OX3 7LE

Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The study monograph will be prepared by the trial management team at the completion of the trial. There are currently no specific plans for publishing the study results.

Intention to publish date
28/02/2019

Individual participant data (IPD) sharing plan
Pseudo-anonymised participant level data will be available on application to the Chief Investigator, once any future definitive study that uses this data has been completed.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	14/11/2017		Yes	No
Results article	results	01/09/2019	27/09/2019	Yes	No
Results article	results	05/05/2019	04/06/2020	Yes	No
Results article	feasibility results	22/07/2019	14/06/2023	Yes	No
Results article	mixed methods process evaluation	09/08/2019	14/06/2023	Yes	No
HRA research summary			28/06/2023	No	No