

Trial of acute femoral fracture fixation

Submission date 26/05/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 26/05/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 14/06/2023	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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

Protocol serial number
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

Intentional

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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**

United Kingdom

England

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

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LS9 7TF

Study participating centre**Nottingham University Hospitals NHS Trust**

Queen's Medical Centre

Derby Road

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NG7 2UH

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Portsmouth Hospitals NHS Trust
Queen Alexandra Hospital
Southwick Hill Road
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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

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

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?
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
Protocol article	protocol	14/11/2017		Yes	No
HRA research summary			28/06/2023	No	No