Trial of acute femoral fracture fixation

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
26/05/2016		[X] Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
26/05/2016		[X] Results		
Last Edited 14/06/2023	Condition category Musculoskeletal Diseases	[] 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 traffix@ndorms.ox.ac.uk

Contact information

Type(s)

Public

Contact name

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Contact details

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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 costeffectiveness 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

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

ΔII

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 NHS Foundation Trus
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

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
<u>Protocol article</u>	protocol	14/11/2017		Yes	No
HRA research summary			28/06 /2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11 /2025	No	Yes