# KFORT:- Knee fix or replacement trial

Submission date 05/11/2015	<b>Recruitment status</b> No longer recruiting
<b>Registration date</b> 05/11/2015	<b>Overall study status</b> Completed
Last Edited 04/11/2019	<b>Condition category</b> Musculoskeletal Diseases

[]	Prospectiv	vely	register	ed
			5	

- [] 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 we get older our bones naturally weaken, and so the elderly are particularly vulnerable to knee pain and injury. Every year, about 5,000-7,000 people over the age of 65 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. It is more effective than simply wearing a cast, as it ensures that the bones heal in the correct position. In order for this treatment to be work properly, patients need to rest and not put any weight on their leg. This can be very difficult, as in particularly elderly patients this process can be very slow due to their weakened bones (osteopenia). An alternative treatment is distal femoral replacement (DFR) surgery. This operation involves removing the section of broken bone and replacing it with man-made implant made from metal or plastic (prosthesis). It has the advantage of a very rapid recovery, and patients are able to put weight on their leg again almost immediately. This type of operation is more common in younger people who have suffered a serious injury, such as a car accident, and so more research is needed to find out if it is a good alternative to surgical fixation in the elderly. The aim of this study is to look at the effects of having DFR surgery or surgical fixation on the recovery of elderly patients with a distal femur fracture.

#### Who can participate?

Adults over 65 years of age with a distal femur fracture, who are suitable for a DFR surgery.

#### What does the study involve?

Participants are randomly allocated to one of two groups. Participants in the first group receive distal femoral replacement surgery. Participants in the second group have an operation which involves surgical fixation of the fracture. The length of time that the participants have to stay in hospital after their surgery is then recorded. Information about the patients (health related questionnaires, complications, length of hospital stay and X-ray pictures) is collected before surgical treatment and at 6 weeks, 6 months and 9 months after their surgery in order to compare the effectiveness of the two treatments.

What are the possible benefits and risks of participating? Participants will benefit from good continuity of care, as they will see a dedicated consultant and research nurse throughout their involvement in the study. Risks of participating include the general risks of undergoing surgery, and being sedated with general anaesthetic.

Where is the study run from? Addenbrookes Hospital and six other NHS hospitals in England (UK)

When is the study starting and how long is it expected to run for? October 2015 to April 2017

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

Who is the main contact? Miss Justyna Romanik

### **Contact information**

**Type(s)** Public

**Contact name** Miss Justyna Romanik

**Contact details** Addenbrookes Hospital Hills Road Cambridge United Kingdom CB2 0QQ

# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 19845

# Study information

#### Scientific Title

KFORT - Knee Fix or Replacement Trial - A feasibility study comparing fixation vs replacement in elderly patients sustaining a distal femoral fracture

#### Acronym KFORT

#### Study objectives

The aim of this study is to compare surgical fixation versus replacement in patients 65 years and older.

**Ethics approval required** Old ethics approval format

**Ethics approval(s)** First Medical Research Ethics Committee, 04/08/2015, ref: 15/WM/0206

**Study design** Multi-centre randomised parallel trial

**Primary study design** Interventional

**Secondary study design** Randomised parallel trial

**Study setting(s)** Other

#### Study type(s)

Treatment

#### 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

Topic: Injuries and emergencies, Musculoskeletal disorders, Ageing; Subtopic: Injuries and Emergencies (all Subtopics), Musculoskeletal (all Subtopics), Ageing; Disease: Injuries and Emergencies, Musculoskeletal, All Ageing

#### Interventions

Participants are randomly allocated to one of two treatments.

Open Reduction and Internal Fixation (ORIF) Group: The patient will undergo fixation, performed by an appropriately trained surgical team. Specific reduction technique, surgical approach and implant selection will not be fixed by the study, but the surgeons must comply with recognised concepts of distal femur fracture fragment reduction and fixation techniques.

Distal Femoral Replacement (DFR) Group: The patient will undergo a DFR performed by an appropriately trained surgical team and complying with recognised concepts of distal femoral replacement.

Information about the patients will be collected before treatment and at 6 weeks, 6 months and 9 months after their surgery within normal NHS hospital settings. This information includes health related questionnaires, complications, length of stay and X-ray pictures; and will allow us to compare the treatments at the end of the study.

#### Intervention Type

Procedure/Surgery

#### Primary outcome measure

Patient reported outcome score is measured using the EQ-5D-5L questionnaire 6 months post injury.

#### Secondary outcome measures

1. Patient reported health outcome is measured using the EQ- 5D- 5L questionnaire at baseline, 6 weeks and 9 months post-surgery

2. Patient reported function and pain outcome is measured using the Oxford Knee score (OKS) at baseline, 6 weeks, 6 months and 9 months post-surgery

3. Patient reported functional outcome is measured using the Disability Rating Index (DRI) at baseline, 6 weeks, 6 months and 9 months post-surgery

4. Adverse events of special surgical interest experienced by the patient will be recorded during surgery and the course of the trial

5. Standard anterior-posterior and lateral radiographs of the knee including the distal femur are taken at baseline, 6 weeks and 9 months after surgery

6. Knee range of motion for knee extension and flexion is measured using a goniometer at 6 weeks and 9 months post-surgery

7. Health economic data is determined by measuring length of hospital stay, complication rates, resource use and societal costs during the course of the trial

#### Overall study start date

01/11/2014

#### **Completion date**

23/10/2018

# Eligibility

#### Key inclusion criteria

1. Aged 65 years or over

2. Informed consent to participate or an agreement from a personal or nominated consultee

- 3. Presence of a closed distal femoral fracture
- 4. Patient considered suitable for distal femoral replacement
- 5. Patient is able to complete trial procedures

#### Participant type(s)

Patient

Age group Adult

**Sex** Both

**Target number of participants** Planned Sample Size: 46; UK Sample Size: 46

#### Total final enrolment

24

Key exclusion criteria
1. Open fracture
2. Previous ipsilateral (same side as fracture) knee replacement
3. Patient is unfit for anaesthesia

Date of first enrolment 23/10/2015

Date of final enrolment 23/04/2017

# Locations

**Countries of recruitment** England

United Kingdom

**Study participating centre Addenbrookes Hospital** Hills Road Cambridge United Kingdom CB2 0QQ

**Study participating centre University Hospital Coventry & Warwickshire** Clifford Bridge Road Coventry United Kingdom CV2 2DX

**Study participating centre Ipswitch Hosptial** Heath Road Ipswich United Kingdom IP4 5PD

Study participating centre

#### Southmead Hospital

Southmead Road Bristol United Kingdom BS10 5NB

**Study participating centre Royal Devon and Exeter Hospital** Barrack Road Exeter United Kingdom EX2 5DW

**Study participating centre The James Cook University Hospital** Marton Road Middlesbrough United Kingdom TS4 3BW

**Study participating centre Stepping Hill Hospital** Poplar Grove Hazel Grove Stockport United Kingdom SK2 7JE

### Sponsor information

**Organisation** Cambridge University Hospitals NHS Foundation Trust

**Sponsor details** Clinical Pharamacology Unit Addenbrooke's Hospital Hills Road Cambridge England United Kingdom CB2 0QQ **Sponsor type** Hospital/treatment centre

ROR https://ror.org/04v54gj93

### Funder(s)

**Funder type** Government

**Funder Name** National Institute for Health Research

### **Results and Publications**

#### Publication and dissemination plan

Planned publication of the feasibility study report in a high impact orthopaedic journal. The results will also be submitted for publication and a report will be disseminated through other peer-reviewed journals, conference presentations and through local mechanisms at all participating centres. A short plain English report for patients and/or their carers, will be co-written by the PPI collaborators.

Intention to publish date 30/06/2019

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Available on request

Study outputs					
Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2019	04/11/2019	Yes	No
HRA research summary			28/06/2023	No	No