

# KFORT:- Knee fix or replacement trial

<b>Submission date</b>	<b>Recruitment status</b>	<input type="checkbox"/> Prospectively registered
05/11/2015	No longer recruiting	<input type="checkbox"/> Protocol
<b>Registration date</b>	<b>Overall study status</b>	<input type="checkbox"/> Statistical analysis plan
05/11/2015	Completed	<input checked="" type="checkbox"/> Results
<b>Last Edited</b>	<b>Condition category</b>	<input type="checkbox"/> Individual participant data
04/11/2019	Musculoskeletal Diseases	

## 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

**Protocol serial number**

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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

**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**

**Ipswich Hospital**

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

### **ROR**

<https://ror.org/04v54gj93>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

National Institute for Health Research

## **Results and Publications**

### **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?
-------------	---------	--------------	------------	----------------	-----------------

<a href="#"><u>Results article</u></a>	results	01/11/2019	04/11/2019	Yes	No
<a href="#"><u>HRA research summary</u></a>		28/06/2023	No		No
<a href="#"><u>Participant information sheet</u></a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes