

KFORT:- Knee fix or replacement trial

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

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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?
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Results article	results	01/11/2019	04/11/2019	Yes	No
HRA research summary			28/06/2023	No	No