ISRCTN16109266 https://doi.org/10.1186/ISRCTN16109266

KFORT:- Knee fix or replacement trial

Submission date
05/11/2015

Recruitment status
No longer recruiting

Registration date
05/11/2015

Overall study status
Completed

Last Edited
04/11/2019

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] 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