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AceFIT – a study comparing three methods of treatment of acetabular fractures (a type of hip fracture) in older patients; surgical fixation versus surgical fixation and hip replacement versus non-surgical treatment

Submission date
30/10/2017

Recruitment status
No longer recruiting

Registration date
28/11/2017

Overall study status
Completed

Last Edited
14/10/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Approximately 1,500 older people break the pelvic part of their hip joint (acetabulum) each year in the UK. These fractures are challenging in older patients as the bone is often fragile and in many pieces. There are 2 main accepted treatment options: non-operative and operative. The operative option can include surgical fixation, or surgical fixation combined with hip replacement. Patients treated non-operatively or with surgical fixation must keep off their injured leg until their fracture has healed. Consequently these patients often have a prolonged recovery time and may have a poorly functioning hip joint after the fracture has healed. Treatment with surgery to replace the hip joint at the same time the fracture is being fixed avoids the problem of a damaged hip joint and most positively enables patients to start walking on their injured leg immediately. Currently we do not know which of these treatments is best. This study compares three treatments; non-surgical treatment, surgical fixation and surgical fixation combined with hip replacement in older patients. The aim of the proposed study is to explore the feasibility of performing a subsequent large scale randomised controlled trial to compare the clinical effectiveness and cost-effectiveness of three different treatment methods of acetabular fractures in older patients; non-surgical treatment, surgical fixation or surgical fixation combined with hip replacement.

Who can participate?
Adults aged 60 years and older who have a displaced acetabular fracture.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group receive a non-surgical treatment (a period of non-weight bearing on the affected leg). Those in the second group undergo surgical fixation treatment (a plate and a screw) and those in the last group undergo surgical fixation combined with a hip replacement. Participants are followed up with

two outpatient visits over a 9 month period to collect information about treatment, recovery and any service or equipment used. Participants are followed up for their quality of life, the function of the hip and the quality of their outcomes.

What are the possible benefits and risks of participating?
The patients will have additional assessments and be more closely monitored than patients not taking part in the study. They will also be given the contact details of the research nurse in case they want to discuss anything about their treatment or the study itself. As part of the study the patient will receive one of three treatments for an acetabular fracture. Two of the treatments, surgical fixation and surgical fixation with hip replacement, involve surgery and anaesthesia and these carry some risks which are the same for each of the procedures and equal to people who have operations for these types of fractures but are not part of this study. The risk from the surgery and anaesthesia is not increased by being in the study. In all patients, the risks of surgery include bleeding, blood clots in legs and lungs, infection, damage to nerves and blood vessels and, rarely, serious complications such as stroke and death. Anaesthesia carries additional risks which are rare and usually very mild; these include dizziness, feeling sick and vomiting, bruising, and shivering. In patients who have fixation of the socket part of the joint, the additional risks due to this operation is that the broken bones move during the healing process and do not heal, this may require another operation and may lead to arthritis in the hip. In patients who have fixation of the socket part of the joint and replacement of the socket part of the hip, the additional risk is that the new joint may dislocate, loosen or become infected which may require an additional operation. In patients who have non-surgical treatment the prolonged period of non-weight bearing can result in overall patient decline in function and possible long term pain. The x-rays patient receives during this study will expose them to radiation which has the potential to increase their risk of developing a cancer. They will however not receive any more radiation by participating in the study than they would have received during their normal care. The amount of radiation they might be expected to receive has a very low risk of cancer and is the same amount of radiation they receive from the environment over about 5 months.

Where is the study run from?
This study is being run by Cambridge Clinical Trials Unit at Cambridge University Hospitals NHS Foundation Trust (UK) and takes place in hospitals in the UK.

When is the study starting and how long is it expected to run for?
July 2017 to June 2020

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

Who is the main contact?
Mr Andrew Carrothers, andrew.carrothers@addenbrookes.nhs.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
35234

Study information

Scientific Title
AceFIT – Acetabular Fractures in older patients Intervention Trial: a feasibility study comparing three methods of treatment of acetabular fractures in older patients, surgical fixation versus surgical fixation and hip replacement versus non-surgical treatment

Acronym
AceFIT

Study objectives

The aim of the proposed study is to explore the feasibility of performing a subsequent large scale randomised controlled trial to compare the clinical effectiveness and cost-effectiveness of three different treatment methods of acetabular fractures in older patients; non-surgical treatment, surgical fixation or surgical fixation combined with hip replacement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
East of England – Essex Research Ethics Committee, 03/10/2017, ref: 17/EE/0271

Study design
Randomised; Interventional; Design type: Treatment, Surgery

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Musculoskeletal Trauma

Interventions
Patients who have sustained an acetabular fracture, fulfil the eligibility criteria and consent to be enrolled on the study are placed at random into one of three groups each with 20 participants. One group receives non-surgical treatment (a period of non-weight bearing on the affected leg), the second group undergoes surgical fixation treatment (a plate and screw) and the third group undergoes surgical fixation combined with hip replacement.

Participants are admitted to an orthopaedic hospital ward prior to undergoing their treatment. If the patient is eligible for the trial and informed consent is signed or consultee agreement is completed a study team member collects information about the patient's injury, general health and background. The EQ-5D-5L outcome score is completed by the participant, or a representative where appropriate. Participants with capacity also complete the Oxford Hip Score (OHS) and the Disability Rating Index (DRI) questionnaires. A study team member arranges the X-ray, which is taken at the hospital admission, to be copied, anonymised and filed in the study notes. The participant is then randomised to have one of the three treatments.

Where the treatment involves an operation (i.e. group two or group three), this is performed by an appropriately trained surgical team in the hospital operating theatre. Surgical data is collected during and at the completion of the patient's surgical procedure. Post-operative care, complications, weight bearing variables and length of hospital stay are also be recorded.

After hospital discharge the participants have two outpatient study visits over a nine month period. As part of normal standard of care participants who have undergone surgical treatment for an acetabular fracture return to the outpatient fracture clinic at six weeks and nine months to have an X-ray and see the doctor in the outpatient fracture clinic. Patient enrolled on the study then see a study team member who collects information on treatment, recovery and any service or equipment used. The patient or proxy complete the EQ-5D-5L, OHS and DRI questionnaire. Ability to walk is also be measured and an anonymised copy of the X-ray taken earlier in the visit are filed in the study file. At six months after their injury, participants are contacted by phone and asked to complete the OHS and DRI questionnaires are also completed by patients with capacity.

Intervention Type
Procedure/Surgery

Primary outcome measure
Health related quality of life is measured using EQ-5D-5L at six months post randomisation

Secondary outcome measures
1. Function and pain with patients is measured using the Oxford Hip Score at nine months
2. Disability is measured using Disability Rating Index at nine months
3. Surgical outcomes are measured using radiographic evaluations at nine months
4. Perioperative physiological variables
5. Ability to walk
6. Qualitative outcome
7. Adverse Events of special interest
All measured at 9 months

Overall study start date
01/07/2017

Completion date
12/10/2020

Eligibility

Key inclusion criteria
1. Male or female aged 60 years or over, including those with cognitive impairment
2. Displaced acetabular fracture where the treating surgeon considers it to be sufficiently displaced to consider surgery (fractures including displacement of anterior column, posterior column or quadrilateral plate, posterior wall with marginal impaction)
3. Informed consent to participate has been obtained from the patient, or agreement from a personal or nominated consultee (in the case of patient who are lacking capacity to consent)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Total final enrolment
60

Key exclusion criteria
1. Open fractures
2. Contra-indication to anaesthesia
3. Patient has a total/partial hip replacement in situ (same side as acetabular fracture)
4. Pre-injury the patient was immobile (i.e. confined to a bed or chair)
5. Polytrauma (patient has significant other injuries likely to have an impact on rehabilitation e.g. bilateral wrist fractures or proximal humerus fracture)

Date of first enrolment
20/11/2017

Date of final enrolment
31/12/2019

Locations

Countries of recruitment
England

United Kingdom

Wales

Study participating centre
Addenbrooke’s Hospital (Lead Centre)
Cambridge University Hospital NHS Foundation Trust
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
The Royal London Hospital
Barts Health NHS Trust
Whitechapel

Greater London
London
United Kingdom
E1 1BB

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Road
Westbury On Trym
Bristol Avon
Bristol
United Kingdom
BS10 5NB

Study participating centre
Walsgrave General Hospital
University Hospitals Coventry and Warwickshire NHS Trust
Clifford Bridge Road
Coventry West Midlands
Coventry
United Kingdom
CV2 2DX

Study participating centre
Queens Medical Centre
Nottingham University Hospitals NHS Trust – Trust Headquarters
Derby Road
Nottinghamshire
Nottingham
United Kingdom
NG7 2UH

Study participating centre
St James's University Hospital
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds West
Yorkshire
Leeds
United Kingdom
LS9 7TF

Study participating centre
University Hospitals of North Midlands NHS Trust
Newcastle Road
Staffordshire
Stoke on Trent
United Kingdom
ST4 6QG

Study participating centre
John Radcliffe Hospital
Oxford University Hospitals
NHS Foundation Trust
Headley Way
Headington Oxfordshire
Oxford
United Kingdom
OX3 9DU

Study participating centre
The James Cook University Hospital
South Tees Hospitals NHS Foundation Trust
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Cardiff and Vale University Health Board
Heath Park
Cardiff
United Kingdom
CF14 4HH

Study participating centre
St George's Hospital
London
United Kingdom
SW17 0QT

Study participating centre

Morriston Hospital
Swansea
United Kingdom
SA6 6NL

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

Sponsor details
Addenbrookes Hospital
Hills Road
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CB2 0QQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04v54gj93

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

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal in 2021.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results	version 1.0	03/07/2019	14/10/2021	No	No
HRA research summary			28/06/2023	No	No