

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	☐ Prospectively registered ☐ Protocol
Registration date 28/11/2017	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 14/10/2021	Condition category Musculoskeletal Diseases	☐ 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?

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Contact information

Type(s)

Public

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised; Interventional; Design type: Treatment, Surgery

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

All

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**

United Kingdom

England

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
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United Kingdom
CV2 2DX

Study participating centre

Queens Medical Centre

Nottingham University Hospitals NHS Trust – Trust Headquarters
Derby Road
Nottinghamshire
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NG7 2UH

Study participating centre

St James's University Hospital

Leeds Teaching Hospitals NHS Trust
Beckett Street
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Study participating centre

University Hospitals of North Midlands NHS Trust

Newcastle Road
Staffordshire
Stoke on Trent
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ST4 6QG

Study participating centre

John Radcliffe Hospital

Oxford University Hospitals
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Headley Way
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Study participating centre
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Study participating centre
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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

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

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?
HRA research summary	version 1.0	03/07/2019	28/06/2023	No	No
Other unpublished results			14/10/2021	No	No