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World hip trauma evaluation five: a randomised controlled trial comparing cemented and uncemented implants for the treatment of displaced intracapsular hip fractures

Submission date
13/03/2017

Recruitment status
No longer recruiting

Registration date
16/03/2017

Overall study status
Completed

Last Edited
26/04/2023

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
A hip fracture is where there is a break in the upper thigh bone (femur). They are very common affecting around 60,000 people each year, particularly in older adults. A hip fracture is a potentially catastrophic event, with approximately 30% of patients dying within a year of the injury and the rest experiencing a significant reduction in their quality of life. The most common type of hip fracture is treated with a partial hip replacement or hemi-arthroplasty. The hemi-arthroplasty can be fixed to the patient's thigh bone with or without the use of 'bone cement'. Cement is the current standard technique, but there are some risks with bone cement which could be avoided by using 'uncemented' implants. These risks, which include an increased risk of death during the first 24 hours after surgery, have prompted a recent alert from the National Patient Safety Agency. Traditionally, early types of uncemented implants led to worse outcomes for patients compared to cemented implants. Now however, there have been significant improvements in uncemented implant technology and the current, limited evidence suggests that these modern implants may be as good as the cemented implants but without the risks of using cement. The aim of this study is test whether there are differences in patients' quality of life following treatment with one of these hemiarthroplasty implants. The study will also test whether one treatment is more cost-effective than the other, and whether either treatment impacts on blood pressure.

Who can participate?
Patients aged 60 and older who have fractured their hip and will receive treatment with a hemiarthroplasty

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo surgery to fix their hip fracture using traditional cemented implants. Those in the second group undergo surgery to fix their hip fracture using modern uncemented hemiarthroplasty implants. Following fixation of their hip fracture, all patients undergo a routine rehabilitation before they

are discharged from hospital. Patients or their carers are asked to complete a questionnaire to assess their quality of life at the start of the study, and then 4 weeks, 4 months and 12 months later. In addition some routinely collected data is sent to the study team, including notes about the operation, discharge details, and blood pressure measurements taken during surgery. After completing the 12-month questionnaire, patients have completed their participation in the study and continue to be treated as per normal standard of care.

What are the possible benefits and risks of participating?
There is no specific advantage to taking part in the study. However, the information from this trial will help provide information about which treatment is best for patients with this type of injury. Any operation for a broken hip carries some risks. The risks of surgery with both implants include: bleeding, infection, further fracture, dislocation, leg length discrepancy, blood clots, damage to nerves and blood vessels, and the risks associated with the anaesthetic. These risks are the same as for patients who are not part of this research project. There are also uncommon risks associated with each type of hip replacement. In a small number of cases, patients having a cemented replacement can have a reaction to the bone cement, and in a small number of uncemented replacements there may be an extension of the fracture during surgery. If either event were to occur, the anaesthetist and surgeon would continue treatment as per normal practice.

Where is the study run from?
1. University Hospital Coventry (UK)
2. Royal Berkshire Hospital (UK)
3. Queen Alexandra Portsmouth (UK)
4. Queen Elizabeth Hospital (UK)
5. John Radcliffe Hospital (UK)
6. Gloucestershire Royal Hospital (UK)
7. Heartlands Hospital (UK)
8. Lincoln County Hospital (UK)
9. Pilgrim Hospital, Boston (UK)
10. Royal Lancaster Infirmary (UK)
11. Royal London Hospital (UK)
12. Southport Hospital (UK)
13. Warwick Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2016 to January 2021 (updated 09/12/2020, previously: December 2020 (updated 10 /12/2019, previously: October 2020))

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

Who is the main contact?
1. Mrs Katy Mironov (public)
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2. Professor Matthew Costa (scientific)
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Study website
ndorms.ox.ac.uk/clinical-trials/current-trials-and-studies/white5

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32748

Study information

Scientific Title
A randomised controlled trial to compare contemporary un-cemented hemiarthroplasty with the standard-of-care cemented hemiarthroplasty for the treatment of displaced intracapsular hip fractures

Acronym
WHiTE Five

Study objectives
Feasibility study:
The aim of this study is to establish the feasibility of conducting a full-scale trial comparing cemented with modern uncemented hemiarthroplasty implants.

Main phase of the study (added 11/04/2018):
The aim of this randomised controlled trial is to compare the health-related quality of life in participants over 60 years of age with a displaced intracapsular hip fracture receiving contemporary uncemented hemiarthroplasty versus the current standard-of-care cemented hemiarthroplasty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Feasibility study: Wales Research Ethics Committee 5, 02/12/2016, ref: 16/WA/0351
2. Main phase: Wales Research Ethics Committee 5, 22/11/2017, ref: 17/WA/0383

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Hip fracture

Interventions

Patients will be randomly assigned a treatment using a web-based randomisation system, this will make sure that about the same number of patients in each participating hospital are assigned each treatment. Patients will then undergo surgery at the next available opportunity on a planned trauma list. The exact surgical procedures will be as per local guidelines. Following surgery patients will undergo a routine rehabilitation programme as per local guidelines.

Cemented hemiarthroplasty: the neck and head of the femur will be replaced with a cemented femoral stem. This is the current standard of care in many UK hospitals

Uncemented hemiarthroplasty: the neck and head of the femur will be replaced with a modern (contemporary) uncemented femoral stem. Uncemented stems are already used as standard practice in some UK hospitals.

Feasibility study:
Participants will be asked to complete a questionnaire during their initial stay in hospital, 1 month after their operation, and 4 months after their operation. This will usually be done in-person or over the telephone, and may be sent by post. If the patient is unable to answer the questions then an appropriate consultee will be asked to answer on the patient's behalf. The short questionnaire is about quality of life before and after the injury, and the amount of care the patient receives.

Main phase of the study (added 11/04/2018):
Participants will be asked to complete a questionnaire during their initial stay in hospital, and 1, 4 and 12 months after their operation. This will usually be done in-person or over the telephone, and may be sent by post. If the patient is unable to answer the questions then an appropriate consultee will be asked to answer on the patient's behalf. The short questionnaire is about quality of life before and after the injury, and the amount of care the patient receives.
Some hospitals will contribute intraoperative and post-operative haemodynamic measurements for enrolled patients. These will be used to determine the feasibility of collecting this data on a larger scale, and to assess any observed difference in haemodynamic parameters between groups.

Intervention Type
Other

Primary outcome measure
Feasibility study:
Recruitment rate, calculated from the number of patients screened and recruited at each participating hospital. Logs of screened and recruited patients monitored monthly.

Main phase of the study (added 11/04/2018):
Quality of life, measured using the EQ-5D-5L score at 4 months post-randomisation

Secondary outcome measures
Feasibility study:
1. Quality of life, measured using the EQ-5D-5L questionnaire at baseline (retrospective/pre-injury), 1 month and 4 months after surgery
2. Trial feasibility, assessed by analysing the reasons given by potential patients who chose not to participate (or who later withdraw), monitored continuously throughout the trial
3. Changes in blood pressure during and immediately after surgery, calculated from routinely collected blood pressure measurements

Main phase of the study (added 11/04/2018):
1. Quality of life, measured using the EQ-5D-5L at 1 and 12 months post randomisation
2. Mortality, measured using routine NHS data at 1, 4 and 12 months post randomisation
3. Functional status, patient-reported during follow-up at 1, 4 and 12 months post randomisation
4. Incidence and cause of revision surgery, patient-reported and from hospital records during follow-up at 12-months post randomisation
5. Complication profile, patient-reported during follow-up at 12-months post randomisation
6. Residential status, patient-reported during follow-up at 1, 4 and 12 months post randomisation
7. Resource use, patient-reported and from hospital records during follow-up at 12-months post randomisation
8. Blood pressure changes during surgery measured using intra-operative haemodynamic measurements at baseline

Overall study start date
01/09/2016

Completion date
31/01/2021

Eligibility

Key inclusion criteria
Feasibility study:
All patients, both those with and without capacity, presenting with an AO type 31-B3 (subcapital, displaced, nonimpacted) fracture of the hip

Main phase of the study (added 11/04/2018):
All patients aged 60 years and older who have fractured their hip and will receive treatment with a hemiarthroplasty

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
Planned Sample Size: 1128; UK Sample Size: 1128

Total final enrolment
1125

Key exclusion criteria
1. Younger than 60 years of age
2. Managed non-operatively
3. Treated with a total hip replacement

Date of first enrolment
10/03/2017

Date of final enrolment
04/12/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University Hospital Coventry
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Royal Berkshire Hospital
Craven Road
Reading
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RG1 5AN

Study participating centre
Queen Alexandra Portsmouth
Southwick Hill Road
Portsmouth
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PO6 3LY

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Birmingham
United Kingdom
B15 2TH

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
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OX3 9DU

Study participating centre
Wexham Park Hospital
Wexham
Slough
United Kingdom
SL2 4HL

Study participating centre
Gloucestershire Hospital
Great Western Road
Gloucester
United Kingdom
GL1 3NN

Study participating centre
Birmingham Heartlands Hospital
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

Study participating centre
Lincoln County Hospital
Greetwell Road
Lincoln
United Kingdom
LN2 5QY

Study participating centre
Pilgrim Hospital
Sibsey Road

Boston
United Kingdom
PE21 9QS

Study participating centre
Royal Lancaster Infirmary
Ashton Suite
Bromley Corridor
Ashton Road
Lancaster
United Kingdom
LA1 4RP

Study participating centre
Royal London Hospital
Whitechapel
London
United Kingdom
E1 1BB

Study participating centre
Southport Hospital
Southport
United Kingdom
PR8 6PN

Study participating centre
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Wexham Park Hospital
Wexham
Slough
United Kingdom
SL2 4HL

Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/052gg0110

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
The results of this trial will be disseminated to the hip fracture clinical community via presentations at national and international meetings as well as publication in peer reviewed journals.

Intention to publish date
31/05/2022

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 22/11/2021:
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

Previous IPD sharing statement:
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version V3	30/07/2018	05/08/2019	No	Yes
Protocol article	protocol	09/12/2019	01/12/2020	Yes	No
Results article		10/02/2022	10/02/2022	Yes	No
Other publications	Economic evaluation plan	13/03/2020	26/04/2023	Yes	No
HRA research summary			28/06/2023	No	No
HRA research summary			28/06/2023	No	No