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An investigation in people aged 60 years and over with a hip fracture to determine whether fixing the broken hip bone or replacing the hip joint gives the patient a better quality of life after 4 months

Submission date
10/05/2021

Recruitment status
No longer recruiting

Registration date
14/05/2021

Overall study status
Ongoing

Last Edited
04/10/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims

Every year around 70,000 people in the UK break their hip. Hip fractures are a common and very serious injury in older patients, similar in impact to a major stroke. This study will investigate two treatments for one specific type of hip fracture. Currently, surgeons either repair the fracture with screws or remove and replace the broken piece of bone, but doctors do not know which is better for patients. This study will examine whether either fixing the broken bone or replacing the hip joint gives a better result for people 60 years and over with hip fractures from at least 40 hospitals across the UK. The researchers want to look at how well people feel and how active they are following their fracture. They will also work out the cost of the two treatments for the individual, for the health service and in terms of social support in the year following the fracture.

Who can participate?

Patients aged 60 and over with a hip fracture that in the opinion of the treating surgeon may benefit from surgical treatment

What does the study involve?

If people agree to take part, they will be allocated using a process called randomisation which makes sure that the groups are similar and the comparison between the two treatments is fair. Participants are randomised to fixing the broken bone or replacing the hip joint. Before and after their operation all the patients will have the usual ward care, rehabilitation and follow up that is standard practice at their hospital.

The researchers will ask patients about their health, pain, walking ability and other daily activities, as well as any complications and specific costs. Their answers will be collected at the outset, and at 6 weeks, 4 months and 1 year after confirmed diagnosis of their hip fracture, and the results from the two groups compared. A few questions will be asked each year for 5 years to find out about any longer-term effects. The researchers will also ask people for their

permission to use de-identified information, which means that it is unlikely that they can be identified from the records received, from national databases that are already being routinely collected.
This study falls under the WHITE Platform framework and has been developed by a team of patient representatives, clinical experts in trauma orthopaedics, study management specialists, experienced statisticians and health economists. The Oxford Clinical Trials Research Unit, based at the University of Oxford, will assure the quality of the study. A monitoring committee of patient representatives and independent experts will oversee the progress and conduct of the study.

What are the possible benefits and risks of participating?
The risks of hip surgery include infection, blood clots, damage to nerves and blood vessels in the surgical area, and the risks associated with the anaesthetic. For hip fixation, there is a risk of requiring further surgery if healing is unsuccessful. For hip replacement surgery, there is a risk of dislocation and of further fracture around the implant. The risks are not altered by taking part in this study.

Where is the study run from?
University of Oxford (UK)

When is the study starting and how long is it expected to run for?
May 2019 to December 2028

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

Who is the main contact?
Rhys Painton
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number
2020-003719-83

IRAS number
287755

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 287755, CPMS 49158, HTA - NIHR128399

Study information

Scientific Title
World Hip Trauma Evaluation – FRUITI: Fix or Replace Undisplaced Intracapsular fractures Trial of Interventions

Acronym
WHiTE 11-FRUITI

Study objectives
To establish if there are differences in health-related quality-of-life (HRQoL) at 4 months post-diagnosis of a hip fracture between patients with a minimally displaced intracapsular fracture treated with an internal fixation or a hemiarthroplasty.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 14/01/2021, Berkshire Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle-upon-Tyne, NE2 4NQ, UK; +44 (0)2071048138; berkshire.rec@hra.nhs.uk), REC ref: 20/SC/0452

Study design
Pragmatic multicentre two-arm randomized superiority comparison with parallel economic analyses follow-up

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 contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Minimally displaced intracapsular hip fracture

Interventions
WHiTE 11-FRUITI is a randomised comparison appended to the World Hip Trauma Evaluation (WHiTE) Platform. WHiTE is a platform trials framework, designed to efficiently deliver multiple randomised comparisons of interventions for patients aged 60 years and over with a hip fracture. The platform and its appended randomised comparisons are governed by one single set of ethical and regulatory approvals and an explicit legal basis and processing purpose for the use of patient-level data. The Platform affords a common core dataset and documentation. Individual randomised comparisons are not dependent on each other and each will have its unique start and stop dates and publication of results without compromising the integrity of the platform.

Participants will be randomised using block randomisation on a 1:1 basis to arthroplasty or internal fixation, stratified by recruitment centre:
1. Arthroplasty: Hemiarthroplasty or total hip arthroplasty. Patient position, surgical approach, implant and surgical technique will be chosen by the operating surgeon.
2. Internal fixation: Sliding hip screw or cannulated screws. Fixation will be achieved using a technique and implant chosen by the operating surgeon.

Longer-term follow-up will be achieved using patient-reported outcomes and routinely collected data at 5 years.

Intervention Type
Procedure/Surgery

Primary outcome measure
Health-related quality of life measured using the EuroQol EQ-5D-5L at baseline (retrospective pre-injury), 6 weeks, 4, 12, 24, 36, 48 and 60 months post-diagnosis of a hip fracture

Secondary outcome measures
1. Subjective mobility status measured using the UK National Hip Fracture Database Mobility Scale at 6 weeks, 4 and 12 months post-diagnosis of a hip fracture
2. Residential status measured using the UK National Hip Fracture Database Residential Status at 6 weeks, 4 and 12 months post-diagnosis of a hip fracture
3. Mortality risk using death notification up to 12 months post-diagnosis of a hip fracture
4. Risk and pattern of complications measured using a bespoke complications questionnaire and routinely collected hospital data up to 5 years post-diagnosis of a hip fracture
5. Resource use from an NHS and personal social services perspective calculated using a bespoke resource use questionnaire up to 12 months post-diagnosis of a hip fracture
6. Pain measured using a visual analogue scale at 6 weeks, 4 and 12 months post-diagnosis of a hip fracture
7. Objective mobility status measured using the Short Physical Performance Battery at 6 weeks post-diagnosis of a hip fracture

Overall study start date
01/05/2019

Completion date
31/12/2028

Eligibility

Key inclusion criteria
Platform inclusion:
All patients 60 years of age and over presenting to a WHiTE recruitment centre for treatment of a hip fracture

Additional inclusion criteria for FRUITI:
A minimally displaced intracapsular hip fracture that in the opinion of the treating surgeon may benefit from surgical treatment

Participant type(s)
Patient

Age group
Senior

Lower age limit
60 Years

Sex
Both

Target number of participants
878

Key exclusion criteria
Platform:
Does not meet inclusion criteria

Additional exclusion criteria for FRUITI:
1. The fracture is only apparent on cross-sectional imaging
2. In the opinion of the treating surgeon the fracture cannot be fixed without a reduction manoeuvre
3. The fracture is complicated by local tumour deposits
4. There is clinically relevant pre-existing osteoarthrosis (OA) of the ipsilateral hip joint

Date of first enrolment
10/06/2021

Date of final enrolment
01/08/2023

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Aintree University Hospital
Lower Lane
Liverpool
United Kingdom
L9 7AL

Study participating centre
Royal Cornwall Hospital
Treliske
Truro
United Kingdom
TR1 3LJ

Study participating centre

Royal United Hospital, Bath
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Southmead Hospital
Southmead Rd
Bristol
United Kingdom
BS10 5NB

Study participating centre
University Hospital of Wales
Heath Park
Cardiff
United Kingdom
CF14 4XW

Study participating centre
James Cook University Hospital
Middlesbrough
United Kingdom
TS4 3BS

Study participating centre
Musgrove Park Hospital
Parkfield Dr
Taunton
United Kingdom
TA1 5DA

Study participating centre
Royal Berkshire Hospital
London Rd
Reading
United Kingdom
RG1 5AN

Study participating centre
Royal Oldham Hospital
Rochdale Rd
Oldham
United Kingdom
OL1 2JH

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

Study participating centre
Stepping Hill Hospital
Poplar Grove
Hazel Grove
Stockport
United Kingdom
SK2 7JE

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
Poole
Poole Hospital
Longfleet Road

Poole
United Kingdom
BH15 2JB

Study participating centre
Conquest Hospital
The Ridge
St. Leonards-on-sea
United Kingdom
TN37 7RD

Study participating centre
Southport and Formby District General Hospital
Town Lane
Southport
United Kingdom
PR8 6PN

Study participating centre
Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
Burton Hospital
Queens Hospital
Belvedere Road
Burton-on-trent
United Kingdom
DE13 0RB

Study participating centre
Luton and Dunstable University Hospital
Lewsey Road
Luton
United Kingdom
LU4 0DZ

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

Study participating centre
Whipps Cross University Hospital
Whipps Cross Road
Leytonstone
London
United Kingdom
E11 1NR

Study participating centre
Horton General Hospital
Trust Unit Offices
Oxford Road
Banbury
United Kingdom
OX16 9AL

Study participating centre
Derriford Hospital
Derriford Road
Derriford
Plymouth
United Kingdom
PL6 8DH

Study participating centre
Basingstoke and North Hampshire Hospitals
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre

Salford Royal Hospital
Stott Lane
Eccles
Salford
United Kingdom
M6 8HD

Study participating centre
William Harvey Hospital
Kennington Road
Willesborough
Ashford
United Kingdom
TN24 0LZ

Study participating centre
Northumbria Specialist Emergency Care Hospital
Northumbria Way
Cramlington
United Kingdom
NE23 6NZ

Study participating centre
Tameside General Hospital
Fountain Street
Ashton-under-lyne
United Kingdom
OL6 9RW

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Glangwili Hospital Child Health Section
Child Health Section
Administration Block

West Wales General Hospital
Carmarthen
United Kingdom
SA31 2AF

Study participating centre
Maidstone and Tunbridge Wells NHS Trust
The Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
Milton Keynes Hospital
Standing Way
Eaglestone
Milton Keynes
United Kingdom
MK6 5LD

Study participating centre
Pilgrim Hospital
Sibsey Road
Boston
United Kingdom
PE21 9QS

Study participating centre
Yeovil District Hospital
Higher Kingston
Yeovil
United Kingdom
BA21 4AT

Study participating centre
Ysbyty Gwynedd Hospital (yg NHS Trust)
Ysbyty Gwynedd
Penrhosgarnedd

Bangor
United Kingdom
LL57 2PW

Study participating centre
Wrexham Maelor Hospital
Croesnewydd Road
Wrexham Technology Park
Wrexham
United Kingdom
LL13 7TD

Study participating centre
Stoke Mandeville Hospital
Mandeville Road
Aylesbury
United Kingdom
HP21 8AL

Study participating centre
Glan Clwd Hospital
Ysbyty Glan Clwydd
Bodelwyddan
Rhyl
United Kingdom
LL18 5UJ

Study participating centre
Royal Stoke University Hospital
Newcastle Road
Stoke-on-trent
United Kingdom
ST4 6QG

Study participating centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
Manchester Royal Infirmary
Cobbett House
Manchester Royal Infirmary
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Frimley Park Hospital
Portsmouth Road
Frimley
Camberley
United Kingdom
GU16 7UJ

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Study participating centre
Kettering General Hospital
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

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

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

Study participating centre
St Helier NHS Trust
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre
Forth Valley Royal Hospital
Stirling Road
Larbert
United Kingdom
FK5 4WR

Study participating centre
Kings College
Valehouse
220 the Vale
London
United Kingdom
NW11 8SR

Study participating centre
Sunderland Royal Hospital
Kayll Road

Sunderland
United Kingdom
SR4 7TP

Study participating centre
Aberdeen Royal Infirmary
Foresterhill Road
Aberdeen
United Kingdom
AB25 2ZN

Study participating centre
Queen Elizabeth Hospital
Stadium Road
London
United Kingdom
SE18 4QH

Sponsor information

Organisation
University of Oxford

Sponsor details
University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD
+44 (0)1865289885
ctrg@admin.ox.ac.uk

Sponsor type
University/education

Website
http://www.ox.ac.uk/

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

Funder Name
NIHR Oxford Biomedical Research Centre

Alternative Name(s)
NIHR Biomedical Research Centre, Oxford, OxBRC

Funding Body Type
Private sector organisation

Funding Body Subtype
Research institutes and centers

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The protocol will be published before recruitment has been completed. The statistical analysis plan will be published before the final data has been collected. The main clinical results and health economic evaluation will be published in high impact peer-reviewed journals after completion of the initial 1 year follow-up period. Further publications are expected to report on the long-term outcomes for these patients.

Intention to publish date
01/03/2029

Individual participant data (IPD) sharing plan
Data access requests should be made to Prof. Matthew Costa (Matthew.costa@ndorms.ox.ac.uk) and Prof. Xavier Griffin (X.griffin@qmul.ac.uk). Requests can be made 2 years after the publication of the trial results. The decision on the level of access granted and the purpose for which it might be made available will be guided by the Oxford Clinical Trials Research Unit and University of Oxford policies regarding data sharing that are in place at the time of the request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 7.0	31/08/2023	02/10/2024	No	No
Protocol file	version 6.0	16/12/2022	02/10/2024	No	No