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WHITE 12-DUALITY: An investigation of people 65 years and over with a broken hip to determine whether using a hip replacement with modified mobility (Dual mobility cup) can reduce the rate of hip dislocation in the first year after hip fracture surgery

Submission date
16/08/2022

Recruitment status
No longer recruiting

Registration date
26/08/2022

Overall study status
Completed

Last Edited
26/08/2022

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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 people, similar in impact to a major stroke. We will investigate two treatments for one specific type of hip fracture. Currently, surgeons use one of two types of total hip replacement, which is an operation to replace both the ball and socket of the hip joint. One type uses a small ball within the socket, in the other the ball is enclosed within a larger plastic ball; we do not know which is the better treatment.

We will investigate which of these treatments gives a better result for people aged 65 years and over with a hip fracture from 30 hospitals across the UK. We want to look at whether people have had any complications after their surgery, particularly dislocation, where the ball comes out of the socket. We will ask people how they feel and how active they are a year after their fracture. We 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 following year.

We have previously tried to answer this important question in a pilot study. We concluded that it wasn't possible to carry out the necessary study since it would need to be very large and expensive. Since then, there has been greatly increased use of the alternative type of hip replacement without any evidence. In this study we will work in collaboration with other international partners so that taken together we will be able to answer the question more quickly and at a cost that is reasonable.

Who can participate?
Patients aged 65 years and over with a displaced intracapsular hip fracture who meet the accepted criteria for consideration of a total hip replacement as per current NICE guidance.

What does the study involve?
To compare the two treatments properly we think we will need 1600 people to take part overall, we anticipate that 450 will come from the UK part of the study. If people agree to take part, they will be placed into one of two groups through a process called randomisation which makes sure that the groups are similar and the comparison is fair. After their operation everyone will have the usual ward care, rehabilitation and follow up that is standard practice at their hospital.

The researchers will ask participants about any complications from the surgery, their health, walking ability and other daily activities, as well as any additional costs. Answers will be collected at the time of the surgery, at 4 and 12 months after the injury; the results from the two groups will then be compared.

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 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?
April 2022 to September 2024

Who is funding the study?
National Institute for Health and Care Research National Institute for Health and Care Research Research for Patient Benefit programme (NIHR RfPB) (UK)

Who is the main contact?
DUALITY Study Team, white12-duality@ndorms.ox.ac.uk

Contact information

Type(s)
Public

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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 53416, RfPB - NIHR203115

Study information

Scientific Title
World Hip Trauma Evaluation 12: Dual mobility versus standard articulation total hip replacement in the treatment of older adults with a hip fracture (DUALITY)

Acronym
WHITE 12-DUALITY

Study objectives
To establish whether the risk of dislocation after total hip replacement (THR) surgery performed for femoral neck fracture is reduced after the use of dual mobility versus standard articulation THR

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/01/2021, Berkshire Research Ethics Committee (Berkshire South Central REC, Easthampstead Baptist Church, Southill Road, Bracknell, RG12 7NS, UK; +44 (0)2071048138; berkshire.rec@hra.nhs.uk), ref: 20/SC/0452

Study design
Pragmatic multicentre two-arm randomized controlled superiority comparison with parallel economic analyses and 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
Displaced intracapsular hip fracture

Interventions
WHiTE 12-DUALITY 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 Dual Mobility Total Hip Replacement or Standard Total Hip Replacement:
1. Dual Mobility Total Hip Replacement: the cup must be of dual articulation, non-constrained design.
2. Standard Total Hip Replacement: the cup and liner must be of a single articulation, non-constrained design.

Intervention Type
Procedure/Surgery

Primary outcome measure
The adjusted risk of dislocation treated by open or closed reduction within 12 months post diagnosis of a hip fracture.
Dislocation events will be obtained through participant-reported complications via medical follow up Case Report Forms and review of the participants' medical records.

Secondary outcome measures
1. Reoperation: any surgical procedure performed on the index total hip replacement within 12 months post diagnosis of a hip fracture
2. Implant-related infection within 12 months post diagnosis of a hip fracture: There is no consistent international consensus on the diagnosis of implant-related deep infection. Here, this will be defined clinically by the treating surgical team, as a diagnosis recorded in the participants' medical records.
3. Subjective mobility status measured using the modified New Mobility Score at 6 weeks, 4 and 12 months post-diagnosis of a hip fracture
4. 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

5. Mortality risk using death notification up to 12 months post-diagnosis of a hip fracture
6. 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
7. 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

Overall study start date
01/04/2022

Completion date
01/09/2024

Eligibility

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

Additional inclusion criteria for DUALITY:
Adults aged 65 years old and over with a displaced intracapsular hip fracture who meet the accepted criteria for consideration of a total hip replacement as per current NICE guidance

Participant type(s)
Patient

Age group
Senior

Lower age limit
60 Years

Sex
Both

Target number of participants
450

Key exclusion criteria
Platform:
Does not meet inclusion criteria

Additional exclusion criteria for DUALITY:
1. Delayed fracture surgery (date of presentation to recruitment centre more than seven days prior to the date of randomisation)
2. Pathological or stress fracture of the femoral neck
3. Fracture adjacent to a previous ipsilateral hip implant, such as a previously inserted screw or plate

Date of first enrolment

10/09/2022

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
England

United Kingdom

Wales

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

Study participating centre
Royal United Hospital, Bath
Combe Park
Bath
United Kingdom
BA1 3NG

Study participating centre
Royal Cornwall Hospitals NHS Trust
Royal Cornwall Hospital
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Sponsor information

Organisation
University of Oxford

Sponsor details

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Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

The protocol will be published before international 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.

Intention to publish date
01/11/2025

Individual participant data (IPD) sharing plan
Data access requests should be made to 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