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A comparison between total hip replacement surgery using the Modular Dual Mobility prosthesis and Standard Exeter prosthesis with associated precautions

Submission date
25/11/2019

Recruitment status
Suspended

Registration date
10/01/2020

Overall study status
Completed

Last Edited
04/01/2021

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Total hip replacement is one of the most commonly performed surgical procedures, with over 87,000 primary hip replacements and 7900 revision hip replacements carried out in the UK each year. Dislocation following total hip replacement is the most common reason for revision within the first year following surgery. Patients are routinely advised to follow hip precautions to restrict hip movement and are provided with equipment to reduce the risk of dislocation in the first few months following surgery.
The Dual Mobility hip replacement is an alternative design of hip replacement that has increased stability and lower risks of dislocation compared to the standard designs routinely used across the UK. The Dual Mobility hip has been used for more than 35 years in Europe and America and more recently in the UK for patients who are considered at high risk of dislocation. However the indications for the use of Dual Mobility implants are expanding to include more active people requiring hip replacement. Due to the inherent stability of the implant patients who have a Dual Mobility hip replacement are not routinely instructed to follow the precautions and therefore are able to move their hip without restrictions as comfort allows. However there are potential benefits of the Dual Mobility hip replacement other than a reduced dislocation rate, such as improved patient satisfaction, faster return to activity and potential overall cost savings to the NHS.
The aim of this study to see if patients receiving a Dual Mobility hip replacement have a better outcome following surgery compared with the current standard hip replacement.

Who can participate?
Patients aged 70 years or older listed for a routine primary total hip replacement for osteoarthritis (not trauma)

What does the study involve?
Patients will be randomly split into two groups. Half will receive the standard hip replacement, and associated precautions to restrict hip movement. The other half will have the Dual Mobility

hip replacement and be advised to move their hip as comfort allows with no restrictions. Patient satisfaction, quality of life and return to functional activity will be compared to see if one group does better than the other.

What are the possible benefits and risks of participating?
Benefits: There are no direct benefits to participants of taking part in this study. The results of this study may benefit future patients undergoing total hip replacement surgery.
Risks: The risks for the two groups are the same as those for any hip replacement surgery. The participants receiving standard hip surgery are at higher risk of dislocation but this is mitigated through routine procedures and not affected by the trial.

Where is the study run from?
Freeman Hospital, UK

When is the study starting and how long is it expected to run for?
September 2019 to June 2022

Who is funding the study?
1. Stryker, UK
2. National Institute for Health Research (NIHR), UK

Who is the main contact?
Karen Smith – research physiotherapist (karen.smith4@nuth.nhs.uk)
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Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
259552

Central Portfolio Management System (CPMS)
40905

Study information

Scientific Title
Modular dual mobility versus standard care (MODUMS) in total hip replacement: a randomised controlled trial

Acronym
MODUMS

Study objectives
The Modular Dual Mobility implant does not improve patient outcomes when compared to a standard fixed bearing implant

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/05/2019, North East – York Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048091; nrescommittee.northeast-york@nhs.net) ref: 19/NE/0085

Primary study design
Interventional

Study design
Randomized; Both; Design type: Treatment, Process of Care, Education or Self-management, Management of Care, Surgery, Rehabilitation, Health Economic

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Hip-joint replacement

Interventions
A single site randomised controlled trial will be conducted to compare the effectiveness of the Dual Mobility hip replacement to the standard fixed bearing hip replacement. The null hypothesis is that the Modular Dual Mobility implant does not improve patient outcomes when compared to a standard fixed bearing implant.

Informed Consent
Written and verbal versions of the Participant Information Sheet and Informed Consent Form will be presented to the participants by the research team. These will explain the exact nature of the study, the implications and constraints of the protocol and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.

The participant will be encouraged to take the study information home and have the opportunity to question the Investigator, their GP or other independent parties to decide whether they will participate in the study.

Participants who decide to take part will be invited to an additional research visit to provide written informed consent. The person who obtained the consent will be a suitably qualified and experienced member of the research team, and have been authorised to do so by the Chief /Principal Investigator.
Copies of the signed Informed Consent will be given to the participants as well as filed in the medical notes.

Participants will be randomly allocated 1:1 to either standard care or the intervention group. Participants randomised to standard care will receive the Exeter Trident 2 fixed bearing implant with standard hip precaution advice and equipment provision. Participants randomised to the intervention group will receive the Modular Dual Mobility hip replacement without hip precautions.

Participants will be followed up at routine clinic appointments at 8 weeks and 12 months post op with an additional postal questionnaire at 6 months post op. After the 12 month follow up the participants will continue with the institutions standard post-operative care.

Research Assessments

Additional Research visit
Participants will be asked to attend a research appointment to provide written informed consent, complete a CRF and a number of pre-operative questionnaires recording their hip function and general health. After completing the baseline assessments participants will be randomised to one of two groups and will be informed of their allocation.

Routine Education Session
All patients will attend a routine education session prior to their hospital admission. At this session participants will be provided with the information about what to expect during their stay in hospital and recovery.
At the end of the session all patients will be advised on the routine use of hip precautions following surgery. As this information is different for the two groups, participants who will receive the Dual Mobility hip will be taken into a different room for the last 10 minutes to receive the information specific to their surgery.

Admission for surgery
All participants will be admitted in line with routine practice. Surgical data, rehabilitation and hospital discharge data will be collected from source data to complete the CRF during the inpatient stay. No additional research assessments will be carried out at this point, however the research team will work closely with the clinical staff (Nurses, Physiotherapist and Occupational Therapists) to ensure that relevant advice and treatment is reinforced depending on the intervention allocation.

Routine Follow up visits
Participants will be expected to attend routine clinical follow up appointments at 8 weeks and 12 months following their surgery. At this point participants will be asked to complete the same questionnaires about their hip function and general health. In addition they will complete questionnaires about any healthcare visits associated with the hip replacement since their previous visit.

Additional Research Review
At the 6 month time point, participants will be asked to complete the same questionnaires as the 8 week and 12 month visit via the post.

Each of the visits outlined above are essential to the successful completion of this study. If participants are already aware of any reason that they will not be able to attend these visits then they will not be able to participate in this study.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Activities of daily living measured using the OHS questionnaire at baseline and 6 months

Key secondary outcome(s)
1. Activities of daily living measured using the OHS questionnaire at baseline, 3, and 12 months
2. Pain, stiffness and functional ability measured by the WOMAC from baseline to 3, 6 and 12 months
3. Satisfaction measured using a validated outcome measure at 3, 6 and 12 months
4. Health-related quality of life measured using the Euro Qol five dimensional (EQ5D-3L) at baseline, 3,6 and 12 months
5. Cost of the two interventions from a UK NHS perspective measured using a health service resource use questionnaire will be completed by the patient at the 8 weeks, 6 and 12 month post-surgical research assessment. Data will be collected on the loan equipment issued by the Trust over the period of the study and the costs associated with this. The tariffs associated with surgery, in-patient stay, follow up visits and any treatment for complications will be retrieved from hospital finance records at the end of the follow-up period.

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. Patients listed for routine primary total hip replacement for osteoarthritis (not trauma)
2. Participants capable of giving informed consent
3. 70 years and over at the time of surgery
4. Suitable for a routine cemented femoral stem and un-cemented acetabular socket

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Previous hip replacement on contralateral side - (already familiar with precautions)
2. Patient presentation that would not be eligible for a routine implant
3. Patient is unable to comply with the study protocol
4. Inability to understand the patient information for the study, provide written informed consent or answer study questionnaires for cognitive or language reasons
5. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study or affect the participant's ability to participate in the study

Date of first enrolment
01/09/2019

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Freeman Hospital
Freeman Road
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Sponsor information

Organisation
The Newcastle upon Tyne Hospitals NHS Foundation Trust

Funder(s)

Funder type
Industry

Funder Name
Stryker

Alternative Name(s)
Stryker Corporation, Orthopedic Frame Company

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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 current data sharing plans for this study are unknown and will be 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			28/06/2023	No	No