ISRCTN11097021 https://doi.org/10.1186/ISRCTN11097021

Feasibility study of hybrid or cemented implants for total hip replacement

Submission date
30/10/2020

Recruitment status
No longer recruiting

Registration date
19/02/2021

Overall study status
Completed

Last Edited
10/05/2022

Condition category
Surgery

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

Plain English summary of protocol

Current plain English summary as of 02/03/2022:
Background and study aims
The hip joint is made up of a ball and socket joint, with the ball being at the head of the thigh bone (femur) and the cup-shaped socket in the pelvic bone. A total hip replacement involves devices being surgically implanted to replace damaged bone within the hip joint and this study is interested in two of the most common types. One type is where both the stem in the thigh bone and the socket in the pelvic bone are cemented in place and the other is where the stem is cemented and the socket is uncemented (called a hybrid implant). Both types of implant are regularly used in similar numbers but little research had been done to establish if one is any better than the other. The aim of this small study is to see if patients who are undergoing hip replacement for osteoarthritis are willing to participate in a study to provide information on how well they consider their new hip to be functioning, and how it affects their day-to-day activities, so that the researchers can decide if a larger study will be achievable to see which implant is better.

Who can participate?
Patients aged 18 and above who are undergoing total hip replacement and for whom either of the study implants are suitable to be used (fully cemented or hybrid)

What does the study involve?
Participants will have the type of implant used selected at random and the researchers will collect information about the operation from clinical notes. At recruitment and 6 weeks and between 3-6 months after their operation participants will be asked to answer questionnaires about the effect their hip replacement has on their day-to-day activity and whether they have had to use NHS services. In addition to this, a mix of people made up of those who took part and those who declined to take part, as well as surgeons and healthcare professionals involved in recruitment and/or data collection, will be interviewed by researchers to learn how recruitment and data collection processes may be developed to improve these aspects in a future trial.

An analysis of cost to the NHS for the treatment of the arthritis and the hip replacement procedure itself will also be carried out. This will be done by comparing what health services (e. g. visits to GP) were required for the six months before and after the surgery.

What are the possible benefits and risks of participating?
The possible risks and benefits of taking part are no different to usual clinical care as the hip implants and study procedures are in line with routine care. Participants will be asked to complete a short set of questionnaires on three occasions (at recruitment and 6 weeks and between 3-6 months post-operation) and some participants, surgeons and healthcare professionals may also take part in interviews with researchers.

Where is the study run from?
Liverpool Clinical Trials Centre (UK)

When is the study starting and how long is it expected to run for?
May 2020 to April 2022

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

Who is the main contact?
Tony Coffey
hiphop@liverpool.ac.uk

Previous plain English summary:
Background and study aims
The hip joint is made up of a ball and socket joint, with the ball being at the head of the thigh bone (femur) and the cup-shaped socket in the pelvic bone. A total hip replacement involves devices being surgically implanted to replace damaged bone within the hip joint and this study is interested in two of the most common types. One type is where both the stem in the thigh bone and the socket in the pelvic bone are cemented in place and the other is where the stem is cemented and the socket is uncemented (called a hybrid implant). Both types of implant are regularly used in similar numbers but little research had been done to establish if one is any better than the other. The aim of this small study is to see if patients who are undergoing hip replacement are willing to participate in a study to provide information on how well they consider their new hip to be functioning, and how it affects their day-to-day activities, so that the researchers can decide if a larger study will be achievable to see which implant is better.

Who can participate?
Patients aged 18 and above who are undergoing total hip replacement and for whom either of the study implants are suitable to be used (fully cemented or hybrid)

What does the study involve?
Participants will have the type of implant used selected at random and the researchers will collect information about the operation from clinical notes. At recruitment and 6 weeks and between 3-6 months after their operation participants will be asked to answer questionnaires about the effect their hip replacement has on their day-to-day activity and whether they have had to use NHS services. In addition to this, a mix of people made up of those who took part and those who declined to take part, as well as surgeons and healthcare professionals involved in recruitment and/or data collection, will be interviewed by researchers to learn how recruitment and data collection processes may be developed to improve these aspects in a future trial.

What are the possible benefits and risks of participating?
The possible risks and benefits of taking part are no different to usual clinical care as the hip implants and study procedures are in line with routine care. Participants will be asked to complete a short set of questionnaires on three occasions (at recruitment and 6 weeks and

between 3-6 months post-operation) and some participants, surgeons and healthcare professionals may also take part in interviews with researchers.

Where is the study run from?
Liverpool Clinical Trials Centre (UK)

When is the study starting and how long is it expected to run for?
May 2020 to January 2022

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

Who is the main contact?
Tony Coffey
hiphop@liverpool.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr Tony Coffey

Contact details
Trial Coordinator
Liverpool Clinical Trials Centre
University of Liverpool
Block C, Waterhouse Building
1-5 Brownlow Street
Liverpool
United Kingdom
L69 3GL
+44 (0)151 794 8929
hiphop@liverpool.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
271885

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 46257, IRAS 271885

Study information

Scientific Title
Feasibility study for a comparative trial of hybrid or cemented implants for total hip replacement. Hip arthroplasty with Hybrid Or cemented implants: Patient-reported outcomes (HipHOP)

Acronym
HipHOP

Study objectives
The aim of this study is to establish the feasibility of performing a randomized controlled trial comparing patient-reported functional outcomes and cost-effectiveness of total hip arthroplasty using either a fully cemented or a hybrid total hip implant.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/08/2020, HSC REC B (Office for Research Ethics Committees Northern Ireland (ORECNI), Customer Care & Performance Directorate, Lissue Industrial Estate West, 5 Rathdown Walk, Moira Road, Lisburn, BT28 2RF, UK; +44 (0)28 95361400 ; recb@hscni.net), ref: 20/NI/0096

Study design
Randomized; Both; Design type: Treatment, Device, Surgery, Qualitative

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Total hip replacement for osteoarthritis

Interventions
Current intervention as of 02/03/2022:
The design of this study incorporates both quantitative and qualitative data collection and analyses, referred to as Workstream 1 (WS1) and Workstream 2 (WS2), respectively. Workstream 1 is the randomized controlled trial comparing the two hip implants by Patient-Reported

Outcome Measures (PROMS); a cost-utility analysis is also included in the PROMS. Workstream 2 is interviews with patients, surgeons and healthcare professionals, designed to obtain their thoughts on the randomized controlled trial. The study has been discussed with a PPI group.

All patients that are approached, regardless of their decision to participate in Workstream 1, will also be invited to participate in Workstream 2 if they meet the eligibility criteria, on which further information is shown below.

Those patients that participate in workstream one will be allocated at random to receive either a fully cemented hip joint (where both the stem and socked are cemented into place) or a hybrid hip joint (where just the stem is cemented and the body forms new bone to hold the socked). They will also be required to complete a portfolio of questionnaires (validated and bespoke) on three occasions. There are six questionnaires in total, though not all of them need to be completed on every occasion.

The first occasion must be prior to them being randomized to the type of hip joint they will receive. If they complete the questionnaires on the day of their surgery, it must also be prior to them receiving any anaesthetic.

The second occasion will be at their routine 6-week postoperative follow-up and the third occasion will be via post at between 3-6 months post operation. If the routine 6-week post-operative consultation if virtual (e.g. due to COVID-19), the questionnaires will be posted to the patient at that timepoint too.

Patients will not need to make any extra visits to hospital than they would for standard care and each will be on study for between 3-6 months post-operatively.

Workstream two will aim to recruit up to 30 patients, 20-30 surgeons and about 6 healthcare professionals to participate in interviews.

Patient interviews will be conducted to gain an understanding of why they chose to participate in workstream one, or not, along with their experiences of being in the study or their perceptions of what it would entail and, in the case of decliners, what the barriers were that prevented them from doing taking part. These interviews will be conducted over the phone. For participants who also take part in workstream 1, these interviews will ideally take place between 2-4 weeks after the patient has undergone their surgery. For decliners, the interview will be arranged at a time convenient to the participant, which could be before or after surgery.

Surgeons that practice at hospitals participating in Workstream 1 (both surgeons who are, and who are not, allowing their patients to be randomised to Workstream 1), and also at other sites that could be considered as recruiting centres for a larger trial will be approached to participate in the workstream two interviews. Initial approach will be made by the Chief Investigator. He will provide a participant information sheet to explain the study and introduce the qualitative researcher, based at the University of Manchester. The purpose of these interviews will be to understand their perceptions of the trial and equipoise, understand factors relating to willingness/unwillingness to take part in a trial, and to identify any other issues that could affect trial findings being implemented into practice. These interviews will be done over the phone.

The third cohort of participants for Workstream 2 are healthcare professionals who approached patients to participate in workstream 1 of the study and/or were involved in data collection. The

purpose of these interviews is to learn about their experiences in recruiting patients and collecting data, and to learn about any changes to the study that may be required to aid recruitment to the larger study. These interviews will be done over the phone.

Previous interventions as of 27/07/2021:
The design of this study incorporates both quantitative and qualitative data collection and analyses, referred to as Workstream 1 (WS1) and Workstream 2 (WS2), respectively. Workstream 1 is the randomized controlled trial comparing the two hip implants by Patient-Reported Outcome Measures (PROMS); a cost-utility analysis is also included in the PROMS. Workstream 2 is interviews with patients, surgeons and healthcare professionals, designed to obtain their thoughts on the randomized controlled trial. The study has been discussed with a PPI group.

All patients that are approached, regardless of their decision to participate in Workstream 1, will also be invited to participate in Workstream 2 if they meet the eligibility criteria, on which further information is shown below.

Those patients that participate in workstream one will be allocated at random to receive either a fully cemented hip joint (where both the stem and socked are cemented into place) or a hybrid hip joint (where just the stem is cemented and the body forms new bone to hold the socked). They will also be required to complete a portfolio of questionnaires (validated and bespoke) on three occasions. There are six questionnaires in total, though not all of them need to be completed on every occasion.

The first occasion must be prior to them being randomized to the type of hip joint they will receive. If they complete the questionnaires on the day of their surgery, it must also be prior to them receiving any anaesthetic.

The second occasion will be at their routine 6-week postoperative follow-up and the third occasion will be via post at between 3-6 months post operation. If the routine 6-week post-operative consultation if virtual (e.g. due to COVID-19), the questionnaires will be posted to the patient at that timepoint too.

Patients will not need to make any extra visits to hospital than they would for standard care and each will be on study for between 3-6 months post-operatively.

Workstream two will aim to recruit up to 30 patients, 20-30 surgeons and about 6 research nurses to participate in interviews.

Patient interviews will be conducted to gain an understanding of why they chose to participate in workstream one, or not, along with their experiences of being in the study or their perceptions of what it would entail and, in the case of decliners, what the barriers were that prevented them from doing taking part. These interviews will be conducted over the phone. For participants who also take part in workstream 1, these interviews will ideally take place between 2-4 weeks after the patient has undergone their surgery. For decliners, the interview will be arranged at a time convenient to the participant, which could be before or after surgery.

Surgeons that practice at hospitals participating in Workstream 1 (both surgeons who are, and who are not, allowing their patients to be randomised to Workstream 1), and also at other sites that could be considered as recruiting centres for a larger trial will be approached to participate in the workstream two interviews. Initial approach will be made by the Chief Investigator. He will provide a participant information sheet to explain the study and introduce the qualitative researcher, based at the University of Manchester. The purpose of these interviews will be to

understand their perceptions of the trial and equipoise, understand factors relating to willingness/unwillingness to take part in a trial, and to identify any other issues that could affect trial findings being implemented into practice. These interviews will be done over the phone.

The third cohort of participants for Workstream 2 are healthcare professionals who approached patients to participate in workstream 1 of the study and/or were involved in data collection. The purpose of these interviews is to learn about their experiences in recruiting patients and collecting data, and to learn about any changes to the study that may be required to aid recruitment to the larger study. These interviews will be done over the phone.

Previous interventions:
The design of this study incorporates both quantitative and qualitative data collection and analyses, referred to as Workstream 1 (WS1) and Workstream 2 (WS2), respectively. Workstream 1 is the randomized controlled trial comparing the two hip implants by Patient-Reported Outcome Measures (PROMS); a cost-utility analysis is also included in the PROMS. Workstream 2 is interviews with patients, surgeons and research nurses, designed to obtain their thoughts on the randomized controlled trial. The study has been discussed with a PPI group.

All patients that are approached, regardless of their decision to participate in Workstream 1, will also be invited to participate in Workstream 2 if they meet the eligibility criteria, on which further information is shown below.

Those patients that participate in workstream one will be allocated at random to receive either a fully cemented hip joint (where both the stem and socked are cemented into place) or a hybrid hip joint (where just the stem is cemented and the body forms new bone to hold the socked). They will also be required to complete a portfolio of questionnaires (validated and bespoke) on three occasions. There are six questionnaires in total, though not all of them need to be completed on every occasion.

The first occasion must be prior to them being randomized to the type of hip joint they will receive. If they complete the questionnaires on the day of their surgery, it must also be prior to them receiving any anaesthetic.

The second occasion will be at their routine 6-week postoperative follow-up and the third occasion will be via post at 6 months post-operation. If the routine 6-week post-operative consultation if virtual (e.g. due to COVID-19), the questionnaires will be posted to the patient at that timepoint too.

Patients will not need to make any extra visits to hospital than they would for standard care and will each be on study for 6 months post-operatively (-1 month/+2 months).

Workstream two will aim to recruit up to 30 patients, 20-30 surgeons and about 6 research nurses to participate in interviews.

Patient interviews will be conducted to gain an understanding of why they chose to participate in workstream one, or not, along with their experiences of being in the study or their perceptions of what it would entail and, in the case of decliners, what the barriers were that prevented them from doing taking part. These interviews will be conducted over the phone. For participants who also take part in workstream 1, these interviews will take place between 2-4 weeks after the patient has undergone their surgery. For decliners, the interview will be arranged at a time convenient to the participant, which could be before or after surgery.

Surgeons that practice at hospitals participating in Workstream 1 (both surgeons who are, and who are not, allowing their patients to be randomised to Workstream 1), and also at other sites that could be considered as recruiting centres for a larger trial will be approached to participate in the workstream two interviews. Initial approach will be made by the Chief Investigator. He will provide a participant information sheet to explain the study and introduce the qualitative researcher, based at the University of Manchester. The purpose of these interviews will be to understand their perceptions of the trial and equipoise, understand factors relating to willingness/unwillingness to take part in a trial, and to identify any other issues that could affect trial findings being implemented into practice. These interviews will be done over the phone.

The third cohort of participants for Workstream 2 are research nurses who approached patients to participate in workstream 1 of the study and/or were involved in data collection. The purpose of these interviews is to learn about their experiences in recruiting patients and collecting data, and to learn about any changes to the study that may be required to aid recruitment to the larger study. These interviews will be done over the phone.

Intervention Type
Procedure/Surgery

Primary outcome measure
Current primary outcome measure as of 27/07/2021:
Recruitment rate measured by the:
1. Total number of patient participants randomised per month
2. Ratio of successful recruitment to eligible patients approached
Timepoint(s): 7 months

Previous primary outcome measure:
Recruitment rate measured by the:
1. Total number of patient participants randomised per month
2. Ratio of successful recruitment to eligible patients approached
Timepoint(s): 12 months

Secondary outcome measures
Current secondary outcome measures as of 27/07/2021:
1. Adherence to the protocol will be measured by:
1.1. The number of minor (e.g. visit time-point violation) or major (e.g. violation of inclusion criteria) protocol deviations collected on a patient participant and site level between randomisation and the defined end of study
1.2. The percentage of patients in each arm that are accidentally unblinded measured between randomisation and the defined end of study
2. Trial withdrawal rate at 6 weeks and 3-6 months will be measured using the total number of patients randomised in the study. In addition, withdrawal rates will be presented by trial withdrawal reasons and withdrawal stage for both arms.
3. Patient participant population characteristics will be measured by collecting the following information:
3.1. Age – at randomisation
3.2. BMI – at randomisation
3.3. Proportion of missing data at the point of final analysis
3.4. Loss to follow up at the point of final analysis
4. Clinical and patient-reported data will be measured by collecting the following information:
4.1. Patient participant-reported outcomes including change in OHS, FJS, WPAI-SHP, SAPS score

and quality of life measured using the EQ-5D- 5LTM at 6 weeks and 3-6 months
4.2. Revision rate, defined as the number of patient participants needing revision arthroplasty within 3-6 months of surgery
4.3. Infection rate, measured as the rate of re-operation for infection within 3-6 months of surgery
4.4. Length of stay, measured in hours between patient admission and initial discharge
4.5. Operation time, measured in minutes as the differences between the start and end of the operation
4.6. Incidence of treatment cross over measured as the surgically reported incidence of a patient receiving an intervention other than the one they were allocated through the randomisation system.
4.7. Incidence of intra-operative surgical complications, the proportion of patient participants experiencing greater than grade III severity will be measured and reported according to Clavien Dindo classification system during patient follow-up
4.8. Incidence of postoperative surgical complications, the proportion of patient participants experiencing greater than grade III severity will be measured and reported according to Clavien Dindo classification system during patient follow-up
5. Completeness of the EQ-5D-5L (Trademark) and Healthcare Resource Use Survey will be measured by using the following methods:
5.1. Descriptive statistics will be used to assess the frequency of missing data for the EQ-5D-5L (Trademark) and Healthcare Resource Use Survey at the point of final analysis.
5.2. Any patterns in missing data will be identified through the use of descriptive statistics at the point of final analysis

Previous secondary outcome measures:
1. Adherence to the protocol will be measured by:
1.1. The number of minor (e.g. visit time-point violation) or major (e.g. violation of inclusion criteria) protocol deviations collected on a patient participant and site level between randomisation and the defined end of study
1.2. The percentage of patients in each arm that are accidentally unblinded measured between randomisation and the defined end of study
2. Trial withdrawal rate at 6 weeks and 6 months will be measured using the total number of patients randomised in the study. In addition, withdrawal rates will be presented by trial withdrawal reasons and withdrawal stage for both arms.
3. Patient participant population characteristics will be measured by collecting the following information:
3.1. Age – at randomisation
3.2. BMI – at randomisation
3.3. Proportion of missing data at the point of final analysis
3.4. Loss to follow up at the point of final analysis
4. Clinical and patient-reported data will be measured by collecting the following information:
4.1. Patient participant-reported outcomes including change in OHS, FJS, WPAI-SHP, SAPS score and quality of life measured using the EQ-5D- 5LTM at 6 weeks and 6 months
4.2. Revision rate, defined as the number of patient participants needing revision arthroplasty within 6 months of surgery
4.3. Infection rate, measured as the rate of re-operation for infection within 6 months of surgery
4.4. Length of stay, measured in hours between patient admission and initial discharge
4.5. Operation time, measured in minutes as the differences between the start and end of the operation
4.6. Incidence of treatment cross over measured as the surgically reported incidence of a patient receiving an intervention other than the one they were allocated through the randomisation system.

4.7. Incidence of intra-operative surgical complications, the proportion of patient participants experiencing greater than grade III severity will be measured and reported according to Clavien Dindo classification system during patient follow-up
4.8. Incidence of postoperative surgical complications, the proportion of patient participants experiencing greater than grade III severity will be measured and reported according to Clavien Dindo classification system during patient follow-up
5. Completeness of the EQ-5D-5LTM and Healthcare Resource Use Survey will be measured by using the following methods:
5.1. Descriptive statistics will be used to assess the frequency of missing data for the EQ-5D-5LTM and Healthcare Resource Use Survey at the point of final analysis.
5.2. Any patterns in missing data will be identified through the use of descriptive statistics at the point of final analysis

Overall study start date
01/05/2020

Completion date
30/04/2022

Eligibility

Key inclusion criteria
Workstream 1:
1. Age 18 years and above
2. Undergoing a primary total hip arthroplasty with either a fully cemented or hybrid implant*
3. Able to give informed consent prior to randomisation
4. Able to communicate in both written and spoken English
* All implants and bone cements that are used must be CE marked and used in accordance with their intended use. There is no limitation as to the manufacturer of prostheses used and surgeons will continue to use the implants that they are familiar with. Furthermore, surgeons will be free to use whichever head/socket material and diameter they feel appropriate. The surgical approach, anaesthetic type, rehabilitation after surgery and other concomitant factors will be as per the surgeons' normal care. These factors will be recorded

Workstream 2:
Patient sample:
5. Have been approached to take part in Workstream 1
Surgeon sample:
6. Consultant orthopaedic surgeon at a Workstream 1 site or a potential site for a future full trial
Research nurse sample - Updated 27/07/2021: Healthcare professional sample:
7. Involved in recruiting to Workstream 1 and/or collecting patient self-reported data

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 89; UK Sample Size: 89

Key exclusion criteria
Workstream 1:
1. Previous surgery to the hip joint
2. All procedures with an indication other than osteoarthritis
3. Patient requiring complex total hip arthroplasty surgery, specifically augmentation of the acetabulum (eg structural bone graft or metal augment) and/or shortening/de-rotational osteotomy of the femur at the time of surgery
4. Patients requiring bilateral simultaneous total hip arthroplasty
5. Vision impairment that precludes the completion of PROMS questionnaires

Workstream 2:
All participants:
6. Hearing impairment that precludes communication by standard telephone

Date of first enrolment
06/01/2021

Date of final enrolment
31/07/2021

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wrightington, Wigan and Leigh NHS Foundation Trust
The Elms
Royal Albert Edward
Infirmary
Wigan Lane
Wigan
United Kingdom
WN1 2NN

Study participating centre
Royal Devon and Exeter NHS Foundation Trust
Royal Devon & Exeter Hospital
Barrack Road

Exeter
United Kingdom
EX2 5DW

Study participating centre
Northumbria Healthcare NHS Foundation Trust
Rake Lane
North Shields
United Kingdom
NE29 8NH

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
University of Manchester
Division of Psychology and Mental Health
Coupland 1 Building
Oxford Road
Manchester
United Kingdom
M13 9PL

Sponsor information

Organisation
Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust

Sponsor details
c/o Linzi Heaton
R&D Department
Wrightington Hospital
Hall Lane
Appley Bridge
Wigan
England

United Kingdom
WN6 9EP
+44 (0)1257256465
researchadmin@wwl.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.wwl.nhs.uk/

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0817-20012

Results and Publications

Publication and dissemination plan
The results of the trial will be disseminated as early as possible, which will include academic journal publications and presentations at academic conferences. Lay summaries of the study findings will be posted to websites. The study design and conduct has been developed with Patient and Public Involvement (PPI). Once the study is complete and results are available, the researchers will once again call on the PPI group to advise on dissemination via non-scientific media, e.g. social media, newspapers local to the sponsor, radio and hospital radio.

Intention to publish date
30/09/2022

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?
Protocol file	version v3.0	29/04/2021	27/07/2021	No	No
Other unpublished results	version 1.0	10/05/2022	10/05/2022	No	No
	version 1.0				

Plain English results	10/05/2022	10/05/2022	No	Yes
HRA research summary		26/07/2023	No	No