The influence of implant length on the outcomes of total hip arthroplasty

Submission date	Recruitment status No longer recruiting	Prospectively registered		
30/06/2017		[X] Protocol		
Registration date	Overall study status Completed Condition category	Statistical analysis plan		
14/07/2017		Results		
Last Edited		Individual participant data		
05/09/2023	Musculoskeletal Diseases	[] Record updated in last yea		

Plain English summary of protocol

Background and study aims

Osteoarthritis is a condition that causes joints to become painful and stiff. Hip osteoarthritis can be treated with hip replacement surgery, where the damaged hip joint is replaced with an artificial implant. The surgeon has various choices as to which implant they use. The implant that surgeons routinely use comes in two different lengths: the original (150mm) length or the 'short' (125mm) length. It is not known whether patient outcomes differ based on the length of the implant used. The aim of this study is to find out whether the length of the hip replacement stem has any influence on pain and physical function after total hip replacement.

Who can participate?

Patients aged 45-80 undergoing total hip replacement for osteoarthritis

What does the study involve?

Participants are randomly allocated to receive either an 'original' (150mm) or 'short' (125mm) stem as part of routine total hip replacement at the study centre. Hip function, quality of life, pain, joint awareness, satisfaction and implant position are measured at the start of the study and after 1 and 2 years.

What are the possible benefits and risks of participating?

It is thought that the length of stem does not affect patient recovery or outcomes after surgery in any way. Participants do not directly benefit from taking part in this study, but the knowledge gained may benefit other people by helping to find the best way to treat people who need total hip replacement in the future. Both stem lengths are available for routine use in the study centres, and as such there are no additional risks in taking part in this study beyond those of having routine total hip replacement surgery.

Where is the study run from?

- 1. Royal Infirmary of Edinburgh (UK)
- 2. Golden Jubilee National Hospital (UK)

When is the study starting and how long is it expected to run for? January 2016 to December 2019

Who is funding the study? Stryker (USA)

Who is the main contact? Dr David Hamilton d.f.hamilton@ed.ac.uk

Contact information

Type(s)

Scientific

Contact name

Dr David Hamilton

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2 (01-04-16)

Study information

Scientific Title

Can Arthroplasty Stem INfluence Outcome? (CASINO): a randomised controlled equivalence trial of 125mm vs 150mm Exeter stems in total hip arthroplasty

Acronym

CASINO

Study objectives

That the use of the 125mm ExeterTM stem in routine total hip arthroplasty achieves equivalent short-term (up to 2 years post-op) patient-reported and radiographic outcomes as the 150mm Exeter stem.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South East Scotland Research Ethics Committee 02, 12/05/2017, ref:16/SS/0176

Study design

Multi-centre prospective randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not currently available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Hip osteoarthritis

Interventions

Patients will be randomised on a 1:1 ratio to receive either an 'original' (150mm) or 'short' (125mm) ExeterTM stem as part of routine total hip arthroplasty at the study centre. Randomisation will be by computer-generated number, stratified by centre using random block sizes.

A standard operative technique will be employed by all trial surgeons; using the posterior approach, ExeterTM femoral component and ContemporaryTM acetabular component (Stryker). All implants will be cemented. The routine post-operative patient care protocol of the study centre will be employed.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Drug/device/biological/vaccine name(s)

150mm ExeterTM hip stem, 125mm ExeterTM hip stem

Primary outcome measure

Patient reported function, measured using the Oxford Hip Score at baseline, 1 year and 2 years

Secondary outcome measures

- 1. Quality of life, measured using the EQ5D-5L questionnaire at baseline, 1 year and 2 years
- 2. Pain, measured using the visual analogue scale at baseline, 1 year and 2 years
- 3. Joint awareness, measured using the Forgotten Joint Score-12 at baseline, 1 year and 2 years
- 4. Satisfaction, measured using a satisfaction Likert response scale at 1 and 2 years
- 5. Radiographic implant position, measured using AP pelvis radiographs at 1 year

Overall study start date

01/01/2016

Completion date

31/12/2020

Eligibility

Key inclusion criteria

- 1. Planned total hip replacement for osteoarthritis
- 2. Planned primary hip arthroplasty with standard implants
- 3. Patients aged 45-80
- 4. Patient willing and able to comply to the study protocol

Participant type(s)

Patient

Age group

Mixed

Lower age limit

40 Years

Upper age limit

80 Years

Sex

Both

Target number of participants

220

Key exclusion criteria

- 1. Dysplasia of the hip/acetabulum
- 2. Requirement for acetabular bone grafting

- 3. Planned bilateral procedures within the trial period
- 4. Activity-limiting pain in either knee or contralateral hip
- 5. Procedures done for pain relief (such as for patients with no walking capacity)
- 6. Already recruited to the trial

Date of first enrolment

01/06/2017

Date of final enrolment

01/06/2018

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre Royal Infirmary of Edinburgh

Edinburgh United Kingdom EH16 4SA

Study participating centre Golden Jubilee National Hospital

Glasgow United Kingdom G81 4DY

Sponsor information

Organisation

ACCORD; The University of Edinburgh & NHS Lothian

Sponsor details

The Queen's Medical Research Institute 47 Little France Crescent Edinburgh United Kingdom EH16 4TJ

Sponsor type

Industry

Website

http://www.accord.scot/

ROR

https://ror.org/01x6s1m65

Funder(s)

Funder type

Industry

Funder Name

Stryker

Alternative Name(s)

Stryker Corporation

Funding Body Type

Private sector organisation

Funding Body Subtype

For-profit companies (industry)

Location

United States of America

Results and Publications

Publication and dissemination plan

Publication of trial results will be sought through high-ranked peer reviewed speciality journals with an expectation of publication 1 year following the end of the last patient follow-up.

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

The current 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?
HRA research summary			28/06/2023	No	No
<u>Protocol article</u>		16/04/2023	05/09/2023	Yes	No