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Short stem total hip arthroplasty for osteonecrosis of the femoral head in patients 60 years or younger: A 3 to 10 year follow-up study

Submission date
14/06/2017

Recruitment status
No longer recruiting

Registration date
04/07/2017

Overall study status
Completed

Last Edited
20/07/2017

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol
Background and study aims
Osteoarthritis of the hip is a common condition that develops with advancing age. It is usually caused by the wear and tear of the cartilage that lines the hip joint, causing bones to rub against each other. This results in pain, stiffness and a loss in mobility. When pain becomes uncontrollable, a total hip replacement (THR) surgery is often performed. This requires for the hip joint to be replaced with a prosthesis (an artificial hip). The prosthesis includes a head and a stem. Typically, the most reliable option is a traiditional stem. However, due to the age of patients requiring hip replacements, a short-stem could allow surgeons to preserve more bone, especially if they need another surgery (revision surgery). There have been a number of short-stem designs. The aim of this study is to review the outcomes of patients who receives a partial neck-retaining short stem and ceramic-on-ceramic bearings in patients younger than 60 to see what the long term impact is.

Who can participate?
Patients younger than 60 years who require hip replacement

What does the study involve?
Eligible participants undergo a hip replacement surgery according to the standard of care. They are given a partial neck-retaining short-stem and either a 32-mm or 36-mm diameter ceramic head is implanted. A ceramic liner is used in all hips. Participants receive the standard postoperative care and are followed up after surgery, one, three, six and 12 months after surgery to assess their symptoms and surgery outcomes and then receive yearly follow up appointments.

What are the possible benefits and risks of participating?
Participants may benefit from receiving the shorter stem prosthesis, which may allow to

preserve more bone stock which is helpful for revision surgery. There are risks associated with THR surgery, however there are no additional risks associated with participating in this study in comparison to an identical patient receiving an identical THR.

Where is the study run from?
University of Cagliari (Italy)

When is the study starting and how long is it expected to run for?
January 2006 to December 2012

Who is funding the study?
Smith and Nephew Orthopaedic (UK)

Who is the main contact?
Prof. Antonio Capone
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
01_2015

Study information

Scientific Title
Short stem total hip arthroplasty for osteonecrosis of the femoral head in patients 60 years or younger: analysis of clinical and radiological results using validated scoring instruments at 3 to 10 year follow-up

Study objectives
The aim of the study is to evaluate short-stem total hip arthroplasties for osteonecrosis of the femoral head in patients 60 years or younger.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, Surgery Department at Cagliari State University, 24/03/2015, ref: verbale4/24/03/2015_13

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Orthopedics; hip arthroplasty; osteonecrosis of the femoral head

Interventions
Participants undergoing total hip arthroplasties (THAs) due to osteonecrosis of the femoral head as part of their normal surgical care are eligible for this study. Participants have their demographic data recorded (age, sex, cause of osteonecrosis) and their osteonecrosis graded according Steinberg Classification.

All patients receive a partial neck-retaining short-stem (NANOS®; Smith and Nephew, Marl, Germany). Either a 32- or 36-mm diameter ceramic femoral head (BIOLOX-forte; CeramTec, Plochingen, Germany) is implanted. A cementless porous-coated acetabular shell (EP-FIT PLUSTM; Smith and Nephew, Marl, Germany), is used in all hips, ranging from 46 to 58 mm. A ceramic liner (BIOLOX-forte; CeramTec, Plochingen, Germany) is placed in all participants.

All procedures are performed through a modified Hardinge approach, in supine position. After femoral head resection, at least 10mm from the base of the great trochanter and perpendicular to the femoral neck, the femoral path is prepared with cancellous bone compactors. The stem is then inserted with a press-fit technique. In all cases, the acetabulum is reamed line-to-line or 1 mm more than the diameter of the component used. Following surgery, the patients are allowed to stand on the first postoperative day and progress to full weight-bearing with crutches. Patients are recommended to use a pair of crutches for 4 weeks.

Clinical and radiographic follow-up is performed at one months, three months, six months, 12 months and then yearly thereafter using validated scored. Evidence of any clicking or squeaking sound emanating from the ceramic-on-ceramic bearing is recorded. Postoperative radiographs are taken to be evaluated for hip geometry restoration (center of rotation, offset and limb length), bone-implant fixation and osteolysis. The stability of the acetabular component, any site of acetabular osteolysis and migration is assessed. Femoral stem fixation is investigated.

Intervention Type
Procedure/Surgery

Primary outcome measure
Clinical outcomes are assessed using the Harris hip score (HHS), the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the UCLA score at baseline, 1, 3, 6, 12 months and yearly for ten years

Secondary outcome measures
Hip geometry restoration (center of rotation, offset and limb length), bone-implant fixation and osteolysis is measured using radiographs at immediately after the surgery and then at 1, 3, 6, 12 months and yearly for ten years

Overall study start date
25/10/2005

Completion date

01/09/2015

Eligibility

Key inclusion criteria
1. Indication for implantation of the Nanos short stem due to osteonecrosis of the hip
2. Patients 60 years old or younger
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
32

Key exclusion criteria
1. Older than 60 years
2. Had a follow up of less than 3 years after the operation

Date of first enrolment
01/01/2006

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Italy

Study participating centre
Clinica Ortopedica, Ospedale Marino
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Sponsor information

Organisation
University of Cagliari (Università degli Studi di Cagliari)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/003109y17

Funder(s)

Funder type
Industry

Funder Name
Smith and Nephew Orthopaedics

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal at the end of 2017.

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Giuseppe Marongiu (giuse.marongiu@gmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/07/2017		Yes	No