

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

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Registration date 04/07/2017	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/07/2017	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 traditional 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?
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Contact information

Type(s)
Public

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Additional identifiers

Protocol serial number

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

Primary study design

Observational

Study design

Observational cohort study

Study type(s)

Treatment

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 month, three months, six months, 12 months and then yearly thereafter using validated scores. 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

Lungomare Poetto 190

Cagliari

Italy

09100

Sponsor information

Organisation

University of Cagliari (Università degli Studi di Cagliari)

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

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