

Minimally invasive surgery in total hip arthroplasty: the two-incision technique versus conventional total hip arthroplasty - a prospective, randomised, controlled trial

Submission date 09/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/01/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 03/11/2008	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR500

Study information

Scientific Title

Study objectives

Anatomy sparing two-incision total hip arthroplasty (THA) has a better functional outcome than conventional THA.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Multicentre, randomised, controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Total hip replacement (THR), arthritis

Interventions

Total hip arthroplasty: conventional lateral approach or two-incision anatomy sparing approach.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The purpose of the study is to scientifically determine the functional effectiveness of anatomy sparing surgery in total hip arthroplasty in comparison with traditional open surgery, measured by the Harris Hip Score.

Secondary outcome measures

1. Number of virtual admission days. Virtual is defined as the number of days until the patient is ready for discharge in the opinion of the surgeon and the patient. Any additional days due to logistic circumstances are not included in this main objective. Virtual discharge criteria are:
 - 1.1. Function, measured in: 50 m walking, walking 1 stairs, getting in and out of bed
 - 1.2. Pain (Visual Analogue Scale [VAS] cm function)
 - 1.3. Wound assessment: including effusion and aspect
2. The Western Ontario and McMaster Universities Osteoarthritis Index
3. Visual Analogue Scale (VAS) is used to measure severity of pain during different activities
4. Use of analgesics
5. The 36-item Short Form Health Survey (SF-36) (pre-operative and at 1 year follow-up)
6. Patient satisfaction
7. Total operation time
8. Number and kind of complications (including wound infection, wound haematoma, dislocations)
9. Need for blood transfusion
10. Wound aspect during treatment period

Overall study start date

01/11/2005

Completion date

01/01/2009

Eligibility

Key inclusion criteria

1. Male or female being 18 years or older
2. Patients meet the criteria for osteoarthritis:
 - 2.1. Pain in hip
 - 2.2. Arthritic changes on radiograph: joint space narrowing femoral/acetabular osteofytes
3. Patients not responding to conservative therapy
4. Written informed consent for study participation

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

110

Key exclusion criteria

1. Patients who are mentally impaired and not able to fill in questionnaires
2. Patients who do not know the Dutch language
3. Patients with a body mass index (BMI) of more than 40
4. Patients with skeletal immaturity
5. Patients with a life expectancy of less than 3 years
6. Patients with altered anatomy resulting in impossibility for the MIS procedure, according to the surgeon e.g.:
 - 6.1. Hip dysplasia with high luxation
 - 6.2. Post-traumatic severe anatomy change
 - 6.3. Post-correction osteotomy
7. Patients with extremity amputation
8. Patients with an active malignant disease or current cytostatic treatment
9. Patients who are participating in another trial
10. Known alcohol or drug abuse

Date of first enrolment

01/11/2005

Date of final enrolment

01/01/2009

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Zimmer, Inc. (USA)

Sponsor details

P.O. Box 708

1800 West Center Street

Warsaw, IN

United States of America
46581-0708

Sponsor type
Industry

Website
<http://www.zimmer.com>

ROR
<https://ror.org/02bn55144>

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration