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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

Registration date
09/01/2006

Overall study status
Completed

Last Edited
03/11/2008

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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