Minimally invasive surgery in total hip arthroplasty: the 2-incision technique vs convemtional total hip arthroplasty. A prospective, randomised, controlled trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25095

Source
NTR

Brief title
N/A

Sponsors and support

Primary sponsor: Zimmer
Source(s) of monetary or material Support: request for funds is in progress

Intervention

Outcome measures

Primary outcome

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

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: -function, measured in: -50m walking, -walking 1 stairs, -getting in and out of bed-Pain (VAS icm function)-Wound assessment: incl. effusion + aspect

-The Western Ontario and McMaster Universities Osteoarthritis Index

-Visual Analogue Scale (VAS) is used to measure severity of pain during different activities. (Corianne kijkt hoe pijnmedicatie en VAS-score te combineren)
Use of analgesics.

-The SF-36 (pre-operative and at 1 year follow-up)

-Patient satisfaction (Corianne: zijn verschillende mogelijkheden)

-Total operation time.

-Number and kind of complications (incl wound infection, wound haematoma, dislocations (main objective gebaseerd op funtionele uitkomst, compl dus geen effect!)

-Need for blood transfusion.

-Wound aspect during treatment period.

Study description

Background summary

N/A

Study objective

anatomy sparing 2-incision total hip arthroplasty (THA) has a better functional outcome than conventional THA.

Intervention

Total hip arthroplasty: conventional lateral approach or 2-incision anatomy sparing approach.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male or female being 18 years or older;

2. Patients meet the criteria for osteoarthritis:

a. Pain in hip;

b. Arthritic changes on radiograph:
joint space narrowing femoral / acetabular osteofytes;

3. Patients not responding to conservative therapy;

4. Written informed consent for study participation.

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 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.:

a. Hip dysplasia with high luxation

b. Post traumatic severe anatomy change

c. 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2005
Enrollment:	110
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-11-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL459
NTR-old	NTR500
Other	: N/A
ISRCTN	ISRCTN77525474

Study results

Summary results
N/A