Total hip arthroplasty by direct anterior approach versus posterolateral approach. A randomized clinical trial.

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Primary objective:Demonstrating that direct anterior approach results in higher patient satisfaction than posterolateral approach in total hip arthroplasty.Secundary objective:-Demonstrating a difference in secundary clinical and functional...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON35973

Source
ToetsingOnline

Brief title
DANTE trial

Condition

- Joint disorders

Synonym
degenerative hip disease, Osteoarthritis of the hip

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Eigen middelen vakgroep orthopedie

Intervention

Keyword: Direct anterior approach, Patient satisfaction, Posterolateral approach, Total hip arthroplasty

Outcome measures

Primary outcome

Patient satisfactory with HOOS-functioning in daily life subscale 6 weeks

postoperative as primary outcome. The definition of success (superiority) for

the individual patient is: a clinical relevant difference is defined as 10

points or more at the HOOS-functioning in daily life subscale.

Secondary outcome

Besides the other 4 HOOS-subscales and HOOS total score, the following

secundary outcomes will be used to evaluate effectivity of both approaches:

- VAS pain en VAS satisfaction

- SF-36

- Clinical data: blood loss, surgery time, incision length, length of hospital

stay

- Radiological: version and inclination cup, version and varus/valgus stem

- Complications: bleeding, infection, dislocation, meralgia paraesthetica,

venous thromboembolism and loosening

Simultaneously course in time of HOOS, VAS en SF36 will be analysed.

Study description

Background summary

A variety of surgical approaches have been proved successful for total hip

arthroplasty (THA). The approaches are posterolateral (Moore or Southern), lateral (Hardinge or Liverpool), anterolateral in supine position (Watson-Jones) or in lateral decubitus position (Mallory) and anterior (Smith-Petersen). Over the past decades the posterolateral and anterolateral approach have predominantly been used for THA. The main reason for world wide use of these approaches was the familiarity to surgeons.
More recently the orthopaedic community has shown significant interest to surgical approaches that lessen trauma to soft tissue and bone in order to allow faster patient rehabilitation and reduced pain. These so-called minimally invasive total hip arthroplasty approaches can be divided into three basic categories: an abbreviated incision (small incision), modifications of standard approaches with smaller incisions and less soft-tissue dissection (less invasive), and novel approaches that reportedly do not cut muscle (minimally invasive).
We believe the single-incision direct anterior approach is the only truly minimally invasive approach for THA. The direct anterior approach (DAA) namely follows intermuscular and internervous planes reaching the hip joint. Potentially this approach leads to reduced blood loss, smaller incisions, reduced pain, shorter hospital stay, faster recovery, more rapidly return to daily activities and a reduced risk of dislocation. However the benefits of different surgical approaches for THA continue to be debated. In this randomized controlled clinical trial will be investigated whether there's a difference in functional, clinical and radiological outcome between the direct anterior approach and the posterolateral approach in THA.

Study objective

Primary objective:
Demonstrating that direct anterior approach results in higher patient satisfaction than posterolateral approach in total hip arthroplasty.

Secundary objective:
- Demonstrating a difference in secundary clinical and functional outcomes between DAA and PLA in THA.
- Demonstrating a difference in radiological outcome between DAA and PLA in THA.
- Demonstrating a difference in number of complications between DAA and PLA in THA.

Study design

Single-centre randomized controlled clinical trial, comparing DAA with PLA. These two groups will be evaluated prospectively, using randomisation with changing block size, stratificated for surgeon subject to allocation concealment.
Patient and surgeon are not blinded, investigator and statistician are blinded for the entire study.

Intervention

Total hip arthroplasties (THA) will be performed by the department of orthopedic surgery in the Isala Clinics, Zwolle (The Netherlands). 120 THA's will be performed in total, of which 60 by posterolateral approach and 60 by direct anterior approach. Both surgeons perform 60 cemented THA's, of which 30 posterolateral and 30 direct anterior.
THA's will be performed with the following compents:
- Stem: Link SP-II
- Cup: Link FAL
- Cup: Biolox ceramic
All patients are subjected to the same preoperative protocol, postoperative rehabilitation and blood- and painmanagement. In every patient systemic profylactic antibiotics (cefazolin 2 gr intravenous) and pharmacological thromboprofylaxis (fondaparinux 0.3mg SC till 5 weeks postoperative) is given. Instruction course in direct anterior approach is required for both surgeons.

Study burden and risks

Conform recent literature one can reasonably assume per-and postoperative complication risk in direct anterior approach is comparable with posterolateral approach.
There's minimal additional effort for patients, only 1 extra hospital visit (3 weeks postoperative) and some patient scores to complete.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Mentally competent men and women with debilitating osteoarthritis of the hip indicated for a total hip arthroplasty
- Signed informed consent
- Age older than 18 years

Exclusion criteria

- BMI > 35
- Contralateral hipprosthesis
- Contralateral , debilitating osteoarthritis of the hip
- Standard contraindications, as prevailing for elective total hip arthroplasty (pregnancy, infection and severe comorbidity of pulmonary, cardiac or metabolic nature)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2012
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	15-09-2011
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
CCMO	NL36220.075.11