Minimally Invasive versus Classical Procedures for Posterolateral and Anterolateral Approaches in Total Hip Arthroplasty. A randomized, double-blinded trial.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22056

Source
NTR

Brief title
MINICLASH

Health condition

Total Hip Arthroplasty, Minimally invasive Surgery.

Sponsors and support

Primary sponsor: No Sponsor
Source(s) of monetary or material Support: No Funding source

Intervention

Outcome measures

Primary outcome

Harris Hip Score.

Secondary outcome

1. SF-36;

2. WOMAC;

3. OHS;

4. Revision and reoperation rate;

5. Haemoglobin;

6. Creatinin kinase;

7. Myoglobin.

Study description

Background summary

Background:
In order to achieve a minimized need for tissue dissection resulting in a faster rehabilitation, minimally invasive surgery (MIS) in Total Hip Arthroplasty (THA) was developed. In this small incision technique the skin and musle dissection has been reduced with respect to the classical approach. Literature shows ambiguous results comparing the posterolateral minimally incisive with the classical approach. As the anterolateral approach is also a routine procedure, and to test how minimally invasive MIS is, we hypothesized that patients treated with a THA using a posterolateral or anterolateral MIS would experience superior clinical results compared with a standard incision after six weeks and no clinical differences after one year. This was tested in a double-blind randomized controlled trial with the Harris Hip Score (HHS) as a primary endpoint.

Methods:
One hundred and twenty consecutive primary uncemented THAs were randomized into one of four groups of 30 patients each. Either standard posterolateral or anterolateral approaches (PL- or AL-CLASS), or minimal invasive posterolateral or anterolateral approaches (PL- or AL-MIS) were performed . CLASS incisions were 18 cm. To avoid postoperative bias, MIS incisions were extended at skin level to 18 cm at the end of the procedure. The HHS as well as patient-centered questionnaires (SF-36, WOMAC and OHS) were obtained preoperatively, at six weeks and one year after the index operation. Preoperative data, blood loss, hemoglobin,

muscle damage parameters and radiological parameters were analyzed. In order to detect a minimal clinically important difference of five points or more between the MIS or CLASS groups with respect to the Harris Hip Score at the 0.05 alpha level with 80% power, 120 patients needed to be enrolled in the study.

Results:
Mean incision length of the THAs performed by MIS was 7.8 (SD = 1.6). In the patients of the MIS group a significant increased mean HHS was observed compared with the CLASS ($p = 0.03$) after six weeks and one year. This difference was caused by the favorable results of the PL-MIS ($p = 0.009$). Of the three patient-centered questionnaires, the SF-36 results were also favourable in the PL-MIS group after six weeks ($p = 0.04$). In the MIS group operation time was longer ($p < 0.001$) and a learning curve was observed based on operation time and complication rate. Peri-operative complications rates were not significantly different between the groups. Blood loss, hemoglobin, muscle damage parameters and radiological parameters also showed no difference.

Conclusions:
This double-blind, randomized study reveals a superior clinical outcome of the PL-MIS compared with the AL-MIS, PL-CLASS and AL-CLASS after six weeks and one year follow-up with the Harris Hip Score as primary endpoint.

Level of Evidence:
Therapeutic Level 1.

Study objective

As the anterolateral approach is also a routine procedure, and to test how minimally invasive MIS is, we hypothesized that patients treated with a THA using a posterolateral or anterolateral MIS would experience superior clinical results compared with a standard incision after six weeks and no clinical differences after one year. This was tested in a double-blind randomized controlled trial with the Harris Hip Score (HHS) as a primary endpoint.

Study design

Preoperative, 2 days, 6 weeks and 1 year postoperative.

Intervention

Minimally Invasive approach in uncemented total hip arthroplasty.

Contacts

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Eligibility criteria

Inclusion criteria

1. Symptomatic coxarthrosis;

2. <70 years of age;

3. BMI <30.

Exclusion criteria

1. No other operations on the ipsilateral hip;

2. BMI >30;

3. Age >70.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2005
Enrollment:	120
Type:	Actual

Ethics review

Positive opinion

Date:	23-03-2009
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	NL1602
NTR-old	NTR1682
Other	CCMO : P005.043L
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A