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

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22056

Bron
Nationaal Trial Register

Verkorte titel
MINICLASH

Aandoening

Total Hip Arthroplasty, Minimally invasive Surgery.

Ondersteuning

Primaire sponsor: No Sponsor
Overige ondersteuning: No Funding source

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Harris Hip Score.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Minimally Invasive approach in uncemented total hip arthroplasty.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Symptomatic coxarthrosis;

2. <70 years of age;

3. BMI <30.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. No other operations on the ipsilateral hip;

2. BMI >30;

3. Age >70.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2005
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	23-03-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1602
NTR-old	NTR1682
Ander register	CCMO : P005.043L
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A