The anterior approach for THA: A (cost-) effectiveness analysis compared to the posterolateral approach

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To assess the clinical and cost effectiveness of the anterior approach, compared to the conventional posterolateral approach for THA in terms of physical functioning and health-related quality of life

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

Summary

ID

NL-OMON43749

Source
ToetsingOnline

Brief title
Cost-effectiveness of the anterior approach for THA

Condition

- Joint disorders

Synonym
Osteoarthritis of the hip

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: Maatschap Orthopedie Martini Ziekenhuis

Intervention

Keyword: Anterior approach, Cost-effectiveness, THA

Outcome measures

Primary outcome

Main study parameter is the Patient Acceptable Symptom State (PASS) which will

be derived from the Hip disabilities and Osteoarthritis Outcome Score (HOOS).

Secondary outcome

Physical functioning and health-related quality of life will be determined

subjectively by means of questionnaires. Additionally, physical functioning

will assessed objectively by means of gait function measurements

Study description

Background summary

Total hip arthroplasty (THA) is considered to be one of the most successful orthopaedic interventions of the past 40 years, with 10-year survival rates exceeding 90%. The number of THAs has increased rapidly during the last decade, because of ageing of Western societies and an increase of the incidence of obesity. Driven by this growing demand for THA, together with a greater emphasis on cost-effectiveness in health care and patients* higher expectations of shorter hospital stays and faster recovery, alternative surgical procedures have been developed to improve the success of THA. The anterior approach for THA is one of these developments. Compared to conventional approaches for THA, such as the posterolateral approach, the anterior approach for THA is considered to result in less damage to soft tissues, such as muscles and tendons, during surgery in order to enhance postoperative recovery and, consequently, in an accelerated return to normal daily functioning. It is expected that elderly patients (aged 70 years and over) may benefit even more from the anterior approach, because of their decreased regenerative capacity to recover from tissue damage. However, there is a lack of well-designed studies, and thus of objective evidence, on the (cost)effectiveness of the anterior approach, with special attention to its effect on elderly THA patients.

Study objective

To assess the clinical and cost effectiveness of the anterior approach, compared to the conventional posterolateral approach for THA in terms of physical functioning and health-related quality of life

Study design

A randomised controlled trial will be executed. Patients will be randomly allocated to undergo THA by means of the anterior approach or the posterolateral approach. The trial will be conducted at the department of Orthopaedics of the Martini Hospital Groningen.

Intervention

Patients in the study group will undergo THA using the minimally invasive single-incision anterior approach. This approach will be compared to the conventional posterolateral approach.

Study burden and risks

Since both the anterior and posterolateral approach for THA are standard approaches for THA, no additional risks are associated with participation of the study. With gait function, walking pattern of the patients is assessed. Patients do not have to perform motor tasks which they are not used to perform. So no risks are involved with the gait function measurements.

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

- Age between 18 - 90 years;
- Indication for THA is primary or secondary symptomatic osteoarthritis.

Exclusion criteria

- A history of previous surgery on the ipsilateral hip;
- symptomatic osteoarthritis of the contralateral hip;
- a hip prosthesis at the contralateral side <= 2 years before;
- symptomatic osteoarthritis of the knee;
- peripheral neuropathy;
- (active) arthritis (e.g. rheumatic disease);
- a history of CVA;
- COPD GOLD III or IV
- NYHA class III or IV
- cognitive impairments;
- not able to fill in questionnaires in the Dutch language.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2015
Enrollment:	260
Type:	Actual

Ethics review

Approved WMO Date:	16-07-2015
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	08-09-2016
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
Other	21941
CCMO	NL53266.099.15