The anterior vs the posterolateral approach for THA: is there a difference in tissue damage?

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To conduct a randomised controlled trial to determine differences in the level of blood markers for tissue damage and to visualize tissue trauma by means of MRI following the anterior approach and posterolateral approach for THA.Additionally, a...

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

Summary

ID

NL-OMON45056

Source
ToetsingOnline

Brief title
Tissue damage following THA

Condition

- Joint disorders

Synonym
osteoarthritis of the hip joint

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: NOREF Annafonds

Intervention

Keyword: anterior approach, posterolateral approach, THA, tissue damage

Outcome measures

Primary outcome

The levels of serum creatine kinase (CK), creatine phosphokinase (CPK), and C-reactive protein (CRP) will be assessed.

For the pilot study the reliability of macrophage and monocyte measurements will be assessed.

Secondary outcome

Tissue damage will additionally be assessed via the enumeration of the tissue macrophages in blood (over time), preferably also using specific antibodies against fragments of tissue-specific proteins, such as soft tissue and skeletal muscle. Multiparameter (* 8 colors) flow cytometry can accurately detect and identify the circulating tissue macrophages with a first set of antibodies against membrane markers. A second set of antibodies will be used to detect the intracellular tissue-specific protein fragments. In case of THA, such tissue-specific protein fragments have to be determined, e.g. derived from soft tissues and/or from skeletal muscle. The absolute and relative numbers of the blood tissue macrophages during and after the THA procedure should be able to give insight into the extent of tissue damage in individual patients.
Besides a relative and quantitative assessment, another secondary study parameter will be the presence of bone- and muscle- specific protein fragments in the circulating macrophages. The presence of these fragments, might be

related to the extent of bone and muscle damage, potentially allowing a more accurate assessment of damage caused by the different THA approaches. Damage to tendons and musculature will be visualized by means of MRI. The amount of fatty atrophy of the muscles and (partial) tendon tears or detachments will be used to measure the actual damage following THA,

Additionally, surgical time and length of hospital stay will be recorded as secondary clinical outcome measures.

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. Tissue damage can be assessed by means of biochemical blood markers such as serum creatine kinase (CK), creatine phosphokinase (CPK), and C-reactive protein (CRP). It is also known that macrophages are key regulators of tissue repair and regeneration. Macrophage activity can therefore be another useful blood marker for the amount of tissue damage. Additionally, changes in muscle cross-sectional area and fatty atrophy of the muscles that can be visualised by means of MRI reflect the muscle damage and correlate with muscle function.

Study objective

To conduct a randomised controlled trial to determine differences in the level of blood markers for tissue damage and to visualize tissue trauma by means of MRI following the anterior approach and posterolateral approach for THA.

Additionally, a pilot study will be performed to assess the reliability the measurements of macrophage and monocyte kinetic activity.

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.

Prior to the start of the RCT a pilot study will be performed to assess the reliability the measurements of macrophage and monocyte kinetic activity.

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 for THA.

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. During hospital stay because of the THA, several blood samples are taken as part of the standard treatment of patients following THA. Because of the study, some extra blood samples are taken during hospital stay and during follow-up. No additional risks are involved with taking these extra blood samples. No additional risks are involved with MRI.

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 of the hip joint

Exclusion criteria

- A history of previous surgery on the ipsilateral hip;
- peripheral neuropathy;
- (active) arthritis (e.g. rheumatic disease);
- a history of CVA;
- a contraindication for MRI;
- cognitive impairments.

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):	01-09-2014
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO Date:	17-10-2013
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	01-09-2014
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	03-10-2016
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
CCMO	NL44369.099.13

Study results

Date completed:	01-07-2016
Actual enrolment:	46