

Longitudinal Leiden Orthopaedics Outcomes of OsteoArthritis Study

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Given the above mentioned gaps in knowledge, the aim of this project is to1) Describe the midterm and long-term outcomes of (primary and revision) total hip, total knee and shoulder replacement surgery in terms of health status as a whole, including...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Joint disorders
Study type	Observational non invasive

Summary

ID

NL-OMON55690

Source

ToetsingOnline

Brief title

LOAS

Condition

- Joint disorders
- Therapeutic procedures and supportive care NEC

Synonym

degenerative joint disease, osteoarthritis

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: divers

Intervention

Keyword: follow-up, multicenter, shoulder prosthesis, total hip, total knee

Outcome measures

Primary outcome

Assessments will be done at baseline (pre-operatively), 3, 6, 12, and 24 months postoperatively and every 2 years thereafter until 10 years post-surgery.

Main outcome parameters are: NRS pain at rest and during physical activity, knee, hip or shoulder functioning (HOOS-PS/KOOS-PS and Oxford Hip/Knee/Shoulder Score); Sleep quality (Pittsburgh Sleep Quality Index (PSQI)), PROMIS physical (Mobility/Upper Extremity) and Cognitive Function; physical activity (Dutch Norm of Healthy Exercise / Fitstandard); work status; Quality of life (SF-12 and EQ-5D); patient satisfaction; health care usage; radiological outcome (post-operative femorotibial angle (knee); alignment of the stem, inclination of the cup (Hip); alignment and orientation of the humeral stem and glenoid., three anchor questions on outcome (Likert scale 0-4) and post-operative complications (including progression of osteoarthritis in other joints and venous thromboembolism).

Main potential determinants of outcome are: sociodemographic characteristics (age, sex); comorbidities (comorbidity questionnaire, Charnley classification and ASA classification); frailty (>70 years of age: Groningen Frailty Index); pre-operative use of pharmacological and non-pharmacological treatment for hip, knee or shoulder pain; outcome expectations (Credibility / Expectancy

Questionnaire); preoperative radiographic osteoarthritis damage (Kellgren score (hip, knee and shoulder), femorotibial angle and alignment of the stem and inclination of the cup (hip) and for the shoulder the Walch score, acromio-humeral distance and rotator cuff status will be measured. patient and surgery characteristics which could predict postoperative complications, (risk factor questionnaires).

Secondary outcome

not applicable

Study description

Background summary

The number of people undergoing total hip, total knee or shoulder replacement surgery is growing. The majority of these patients has a favorable outcome with respect to pain, function and quality of life. In a small group of patients however the results are disappointing. Until now, despite the availability of hip, knee and shoulder registries and a considerable number of studies on the outcomes in terms of prosthesis survival, joint function and quality of life, few studies have focused on the impact of total hip, knee and shoulder surgery on societal participation (physical activity, sports, paid and unpaid work) and on health care usage, including rehabilitation. Information to patients on more general less favourable outcomes, ranging from complications to the sequelae after joint replacement surgery is often lacking. For that matter, an analysis of including patient reported outcome before and after revision surgery, progression of osteoarthritis in other joints (after the replaced joint) as well as presence of more general complications like and venous thromboembolism are important before a patient can make well balanced decision with his orthopaedic surgeon to have a joint arthroplasty. These collected data will give input to preventive measures reducing less favourable outcome to patients, is lacking as well. Moreover, concerning the predictors of outcome, currently available studies did not comprehensively include the role of personal factors such as treatment expectancies nor preoperative pain sensitisation on outcome.

Study objective

Given the above mentioned gaps in knowledge, the aim of this project is to

1) Describe the midterm and long-term outcomes of (primary and revision) total hip, total knee and shoulder replacement surgery in terms of health status as a whole, including the levels of body functions and structures, daily activities, participation in society, health care usage, and complications of joint replacement surgery, such as venous thrombosis as well as progression of the *disease* osteoarthritis in other joints.

2) Determine which factors predict the outcomes of elective primary and revision total hip, total knee and shoulder replacement surgery, as mentioned under aim 1.

The results of this analysis will contribute to a better selection of patients who will profit most from elective primary and revision total hip, total knee and shoulder replacement surgery and to tailored rehabilitation treatment strategies, as well as prevention of complications after joint replacement surgery.

The aims will be achieved by setting up a structure for building a large, standardized database regarding the outcomes of hip, knee and shoulder replacement surgery, called LOAS (Longitudinal Leiden Orthopaedics Outcomes of Osteoarthritis Study). The structure of this database will be aimed to be like *The String of Pearls Initiative* (*Het Parelsnoer Initiatief*, www.parelsnoer.org).

Study design

This project has a multicenter, longitudinal (prospective) design, and includes all consecutive patients undergoing hip or knee surgery in 9 general hospitals and one university hospital in the region Zuid-Holland, Noord-Holland and Overijssel in The Netherlands. The duration of the study is 23 years in total, with the inclusion period being 13 years and the duration of follow-up 10 years. For longer-term follow-up additional ethical consent will be requested.

Study burden and risks

This study is observational in nature, is embedded in standard treatment (primary total hip, total knee or shoulder arthroplasty surgery in patients with hip, knee and shoulder osteoarthritis) and mainly consists of questionnaires.

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

- Patients, who are scheduled for primary total hip, total knee or shoulder arthroplasty surgery or revision surgery
- Are able to complete questionnaires, either on paper or electronically
- Patients > 18 years of age

Exclusion criteria

- No informed consent signed or electronic informed consent provided
- Insufficient Dutch language skills
- Physical or mental status not allowing participation

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Health services research

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-06-2012

Enrollment: 17000

Type: Actual

Ethics review

Approved WMO

Date: 07-05-2012

Application type: First submission

Review commission: METC Leiden-Den Haag-Delft (Leiden)

metc-ldd@lumc.nl

Approved WMO

Date: 25-05-2012

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 11-06-2012

Application type: Amendment

Review commission: METC Leiden-Den Haag-Delft (Leiden)

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Approved WMO

Date: 21-05-2013

Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 11-11-2014
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 20-02-2015
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 27-03-2017
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 29-07-2019
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 27-01-2020
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 04-02-2021

Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 21-05-2021
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 28-01-2022
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO
Date: 31-12-2024
Application type: Amendment
Review commission: METC Leiden-Den Haag-Delft (Leiden)
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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	NL39663.058.12
Other	TC=3348