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	Recruitment started
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: Leids Universitair Medisch Centrum

Intervention

- No intervention

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

Explanation

N.a.

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 (Pitsburg 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 osteoarthritisdamage (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.

Intervention

n.v.t.

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

Trial sites in the Netherlands

Groene Hart Ziekenhuis
Target size: 1200

Reinier de Graaf Groep
Target size: 150

Diaconessenhuis Leiden
Target size: 1000

Leids Universitair Medisch Centrum
Target size: 1000

Langeland Ziekenhuis, Zoetermeer
Target size: 2500

Albert Schweitzer Ziekenhuis
Target size: 2500

Waterland Ziekenhuis
Target size: 600

Orthopedisch Centrum Oost-Nederland
Target size: 800

Rijnland Ziekenhuis
Target size: 3500

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 phase:	N/A
Study type:	Observational non invasive
Intervention model:	Single
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	01-06-2012
Enrollment:	17000
Duration:	120 months (per patient)
Type:	Actual

Medical products/devices used

Product type:	N.a.

IPD sharing statement

Plan to share IPD: Yes

Plan description
N.a.

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) metc-ldd@lumc.nl

Approved WMO Date:	11-06-2012
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-05-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	11-11-2014
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	20-02-2015
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	27-03-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	29-07-2019
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	27-01-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	04-02-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	21-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	28-01-2022
Application type:	Amendment

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	31-12-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	31-03-2025
Application type:	Amendment
Review commission:	METC LDD

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	TC=3348
CCMO	NL39663.058.12
Research portal	NL-008389