Foot complaints in patients undergoing total hip or knee arthroplasty (THA or TKA)

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To determine:* The occurrence of foot and ankle complaints in patients who are undergoing THA or TKA* The occurrence of radiographic OA of the forefoot, midfoot and ankle in patients who are undergoing THA or TKA* The association between foot and…

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

Summary

ID

NL-OMON43530

Source
ToetsingOnline

Brief title
Foot complaints in patients undergoing total hip or knee arthroplasty

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym
hip artroplasty, hipprothesis, knee artroplasty, kneeprothesis

Research involving
Human

Sponsors and support

Primary sponsor: Rijnland Ziekenhuis
Source(s) of monetary or material Support: Fonds Wetenschapscommisie Alrijne

Ziekenhuis

Intervention

Keyword: footcomplaints, total hip artroplasty, total knee artroplasty

Outcome measures

Primary outcome

Assesments will be done at baseline (pre-operatively) and one year postoperative,

Main outcome parameters are:

- FOAS

- FFI

- extra questions will evaluate multi-joint involvement, foot and ankle complaints and the presence of comorbidities like polyneuropathy. Also the use of orthopaedic insoles or modified/custom-made shoes and previous trauma will be asked

Besides patients will be asked for additional preoperative basic foot and ankle radiographic examination. These X-rays are done at the preoperative visit and will consist of an anterior-posterior view, a lateral view and a Mortise-view of each foot. Foot and ankle X-rays are scored using the Kellgren and Lawrence score.

Moreover all patients will have physical foot and ankle examination on the attendance of signs of osteoarthritis by the presences of clavus, hammer-toes or hallux valgus.

Secondary outcome

Secundary parameters are the LOAS questionnaires:

Knee or hip functioning (HOOS/KOOS and Oxford Hip/Knee Score, Knee instability questionnaire); physical activity (Sport, hobbies and volunteering questionnaire and Dutch Norm of Healthy Exercise / Fitstandard, accelerometer); work status; Quality of life (SF-12 and EQ-5D); patient satisfaction; health care usage; radiological outcome (post-operative femorotibial angle (knee) and alignment of the stem and inclination of the cup (Hip) and post-operative complications.

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 or knee pain; outcome expectations (the New York Hospital for Special Surgery Questionnaire);

Study description

Background summary

The number of people undergoing total hip or total knee 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, between 7-34%. Until now, despite the availability of hip and knee registries and a considerable number of studies on the outcomes in terms of prosthesis survival, hip and knee function and quality of life, few studies have focused on the impact of total hip and knee surgery on societal participation (physical activity, sports, paid and unpaid work) and on health care usage, including rehabilitation.
The LOAS study, started in Leiden in 2014, is focused on the possible predictors in outcome after THA or TKA surgery. The reported foot and ankle complaints are most likely to be related to foot and ankle osteoarthritis as

this condition is relatively common. However, so far little is known on the presence of clinical and radiological foot and ankle osteoarthritis in patients undergoing Total Hip or Knee Arthroplasty (THA/TKA).

Study objective

To determine:
* The occurrence of foot and ankle complaints in patients who are undergoing THA or TKA
* The occurrence of radiographic OA of the forefoot, midfoot and ankle in patients who are undergoing THA or TKA
* The association between foot and ankle complaints and the severity of radiographic OA of the forefoot, midfoot and ankle and presurgery and postsurgery outcomes.

Study design

This study is an addition to the Longitudinal Leiden Orthopeadics and Outcomes of Osteoarthritis Study (LOAS), a larger prospective, multicenter cohort study including patients undergoing primary THA or TKA. The current project will have a prospective design and will only run in the Alrijne Hospital for a limited time period of 12 months starting in Februari 2016. All patients scheduled for THA or TKA and are taking part in the LOAS study (minimum of 178 THA patients and 178 TKA patients with hip or knee osteoarthritis, our aim is 200 patients in each group) are eligible for the present study. This sample size is determined on 178 in each group (THA and TKA) based on a power of 0.80 and an effect size of 0.3 (medium).

Study burden and risks

This study is observational in nature, is embedded in standard treatment (primary total hip or total knee surgery in patients with hip or knee osteoarthritis) and consists of questionnaires (FFI and FAOS with supplement questions) which patients can answer when at the pre-operative contact.
The extent of the burden and risk of the patients is nil.
The additional five X-rays of the foot and ankle (Mortise view, AP and Lateral view) will add an effective dose of 3,47E-04milliSv of radiation.
The highest mortalityrisk due to radiationbased tumours is 8.27 E -07%. So the increase of effective dose is nil.

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

All patients scheduled for THA or TKA and are taking part in the LOAS study (minimum of 178 THA patients and 178 TKA patients with hip or knee osteoarthritis, our aim is 200 patients in each group) are eligible for the present study.

Exclusion criteria

< 18 year of age
not capable of answerring the questionnaires
not capable of understanding Dutch language

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2016
Enrollment:	400
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-07-2016
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL56450.058.16