Long-term outcomes of total hip and knee arthroplasties.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22630

Bron
NTR

Aandoening

osteoarthritis, arthritis, total hip prosthesis, total knee prosthesis

Ondersteuning

Primaire sponsor: LUMC, Leiden
Rijnland Ziekenhuis, Leiderdorp
Diaconessenhuis, Leiden
Groene hart ziekenhuis, Leiden
Lange land ziekenhuis, Zoetermeer
Overige ondersteuning: Reumafonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Knee or hip functioning (HOOS/KOOS);

2. Physical activity (SQUASH questionnaire, accelerometer);
3. Work status;
4. Quality of life (SF-12 and EQ-5D);
5. Patient satisfaction;
6. Health care usage;
7. Radiological outcome (post-operative femorotibial angle (knee) and alignment of the stem and inclination of the cup (Hip) and post-operative complications.

Toelichting onderzoek

Achtergrond van het onderzoek

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. 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. Moreover, concerning the predictors of outcome, currently available studies did not comprehensively include the role of personal factors such as treatment expectancies.

Objective:

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

1. Describe the midterm and long-term outcomes of total hip and knee surgery in terms of health status as a whole, including the levels of body functions and structures, daily activities, participation in society and health care usage;

2. Determine which factors predict the outcomes of total hip and knee surgery.

The results of this analysis will contribute to a better selection of patients who will profit most from hip and knee surgery and to tailored rehabilitative treatment strategies.

The aims will be achieved by setting up a regional structure for building a large, standardized database regarding the outcomes of total hip and total knee 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 5 general hospitals and one university hospital in the region Zuid-Holland, The Netherlands.

Study population:

Patients, who are scheduled for primary total hip or total knee surgery or revision surgery, are fluent in Dutch and are able to complete questionnaires, either on paper or electronically.

Main study parameters/endpoints:

Assessments will be done at baseline (pre-operatively 6, 12, and 24 months postoperatively and every 2 years thereafter.
Main outcome parameters are: Knee or hip functioning (HOOS/KOOS); physical activity (SQUASH questionnaire, 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.
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 or knee pain; outcome expectations (the New York Hospital for Special Surgery Questionnaire); preoperative radiographic damage (Kellgren score, Femorotibial angle and alignment of the stem and inclination of the cup) and hand grip strength.

Participating centers:

1. Rijnland Ziekenhuis, Leiderdorp: Drs. S.H.M. Verdegaal, orthopaedic surgeon;

2. Diaconessenhuis, Leiden: Dr. R. Krips, orthopaedic surgeon;

3. Groene hart ziekenhuis, Leiden: Drs. R Onstenk, orthopaedic surgeon;

4. Lange land ziekenhuis, Zoetermeer: Drs. H.Kaptijn, orthopaedic surgeon;

5. Reinier de Graaf Gasthuis, Delft: dr. S.B.W. Vehmeijer, orthopaedic surgeon;

6. LUMC, Leiden: drs. H.M.J. van der Linden-van der Zwaag, orthopaedic surgeon.

7. Albert Schweitzer Ziekenhuis, Dr. W.J. Marijnissen, orthopaedic surgeon

Doel van het onderzoek

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. 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. Moreover, concerning the predictors of outcome, currently available studies did not comprehensively include the role of personal factors such as treatment expectancies.

Onderzoeksopzet

Assessments will be done at baseline (pre-operatively), at operation (intra-operatively) and 6, 12, and 24 months postoperatively and every 2 years thereafter.

Onderzoeksproduct en/of interventie

The investigational product is the standard procedure (usual clinical care) for total hip replacement or total knee replacement.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. All patients who are scheduled for primary total hip or total knee surgery or revision surgery;

2. Are able to complete questionnaires, either on paper or electronically;

3. Patients > 18 years of age.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. No informed consent signed;

2. Insufficient Dutch language skills;

3. Physical or mental status not allowing participation.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-05-2012
Aantal proefpersonen:	4500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	13-03-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3197
NTR-old	NTR3348
Ander register	METC LUMC : 12.047
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A