Total knee arthroplasty, the long and mid term follow up.

Gepubliceerd: 12-02-2014 Laatst bijgewerkt: 18-08-2022

We hypothesize that the Vanguard TKA show similar and comparable outcome measures and survival as the Maxim TKA

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

Samenvatting

ID

NL-OMON28404

Bron
NTR

Verkorte titel
TKA, Vanguard, Maxim, Survival, mid term, long term

Aandoening

osteoarthritis, knee joint is cartilage wear, Knee Arthrosis, Post-traumatic arthritis

Ondersteuning

Primaire sponsor: Department of Orthopaedic Surgery, Orbis Medisch Centrum, Sittard-Geleen, the Netherlands
Overige ondersteuning: Stichting ter bevordering van de orthopedische kwaliteit.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Comparing the initial and long- and mid term survival of the Maxim and Vanguard TKA.
The primary endpoint will be defined as revision of the the Maxim or Vanguard TKA for any

kind.
o Adverse events: all postoperative adverse events related to the implant will be evaluated and
compared between both groups.

Toelichting onderzoek

Achtergrond van het onderzoek

The mid- and long term survival and patient reported outcome measures (PROMs) for this prosthesis are unknown. The revision rate of an implant is an important outcome measure in evaluating survival of a new TKA design. To make survival data comparable between different prostheses designs, revision is used as a failure end-point. The rate of 'Revisions per 100 observed component years' can then be calculated. According to a recent study which combined the national databases of 6 different countries there are 1.26 revisions per 100 observed component years. This number is the average revision rate for different knee designs in multiple countries. Clinical studies are valuable in addition to registry data as they can provide more details on the study population, the procedure and other aspects of the outcome. If the early survival rate of the Vanguard is known, and is comparable with other prostheses as well as its predecessor the Maxim, this would justify further use of the Vanguard TKA.

Doel van het onderzoek

We hypothesize that the Vanguard TKA show similar and comparable outcome measures and survival as the Maxim TKA

Onderzoeksopzet

5 and >10 years follow up

Onderzoeksproduct en/of interventie

the Maxim total knee System (Biomet) will be compared with a cohort of consecutive patients utilizing the Vanguard total knee
System (Biomet)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Operated between January 1999 and December 2002 (Maxim group)
- Operated between June 2006-december 2008 (Vanguard group)
- Completed the full follow up
- Deceased with a known TKA revision

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients who did not completed the full follow up
- Deceased without a known TKA revision

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Cross-over
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	07-02-2014
Aantal proefpersonen:	1500
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-02-2014
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	NL4237
NTR-old	NTR4382
Ander register	: 13N102

Resultaten