Radiological evaluation of CT vs MRI based Signature™ for total knee arthroplasty
A Prospective, Randomized Study

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• CT based Signature™ will result in a comparable percentage of prosthesis that is placed correctly (within guidelines of 3 degrees varus and 3 degrees valgus). • CT-based Signature™ will result in a comparable alignment of the prosthesis as...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23068

Bron
Nationaal Trial Register

Verkorte titel
CT, MRI, Patient Specific, TKA

Aandoening

Patients who require TKA as a result of osteoarthritis of the knee and are candidates for the Vanguard TKA system.

Ondersteuning

Primaire sponsor: Orbis
Overige ondersteuning: NA

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Outliers in alignment of the femoral and tibial prosthesis in the frontal plane, measured on radiographs made 6 weeks after operation and compared between the CT-based Signature™ procedure and the standard MRI-based Signature™

Toelichting onderzoek

Achtergrond van het onderzoek

-

Doel van het onderzoek

• CT based Signature™ will result in a comparable percentage of prosthesis that is placed correctly (within guidelines of 3 degrees varus and 3 degrees valgus).

• CT-based Signature™ will result in a comparable alignment of the prosthesis as calculated by software and the actual alignment in vivo after knee surgery.

• CT-based Signature™ will result in comparable changes of plans.

• CT-based Signature™ will result in result in comparable percentages of outliers of the limb and of the individual prosthesis components.

Onderzoeksopzet

Pre-, 6 weeks post and 1 year post operative

Onderzoeksproduct en/of interventie

TKA aligned either with the CT based Signature™ or the MRI based Signature™ alignment guide.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients scheduled to undergo primary TKA replacement with any of the following indications

• Painful and disabled knee joint resulting from osteoarthritis.

• High need to obtain pain relief and improve function,

- Body-mass-index (BMI) <35

- Ability and willingness to follow instructions, including control of weight and activity level, and to return for follow-up evaluations.

- Consent form read, understood and signed by patient.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Active infection in knee

- General infection

- Distant foci of infections which may spread to the implant site

- Failure of previous joint replacement

- Pregnancy

- Previous major knee surgery, except for arthroscopic meniscectomy.

- Metal near knee joint (MRI-scan not possible)

- Not able or willing to undergo MRI-scan or CT-scan

- Rheumatoid arthritis

- Non-correctable varus axis

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2014
Aantal proefpersonen:	140
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-08-2014
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	NL4566
NTR-old	NTR4734
Ander register	- : 13T174

Resultaten

Samenvatting resultaten

Schotanus, M. G. M., et al. "A radiological analysis of the difference between MRI-and CT-based patient-specific matched guides for total knee arthroplasty from the same manufacturer." Bone Joint J 98.6 (2016): 786-792.