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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23068

Source
Nationaal Trial Register

Brief title
CT, MRI, Patient Specific, TKA

Health condition

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

Sponsors and support

Primary sponsor: Orbis
Source(s) of monetary or material Support: NA

Intervention

Outcome measures

Primary outcome

• 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™

Secondary outcome

• Fit and practical use of the guides

• Needed change of plans and reasons for changes

• Occurrence (and percentage) of outliers in alignment in the frontal, sagittal and horizontal plane of femoral and tibial components.

• Occurrence (and percentage) of outliers in alignment of the mechanical axis of the leg.

• Difference in thickness between the in vivo inserted polyethylene and the pre-operatively calculated thickness of this insert.

• Accurateness of guides: deviations from pre-operative digital plan.

Study description

Background summary

-

Study objective

• 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.

Study design

Pre-, 6 weeks post and 1 year post operative

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2014
Enrollment:	140
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-08-2014
Application type:	First submission

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-new	NL4566
NTR-old	NTR4734
Other	- : 13T174

Study results

Summary results

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.