Comparison between CT- and MRI-based Patient specific matched instruments for total knee arthroplasty

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26489

Source
NTR

Brief title
CT and MRI based matched instruments

Health condition

knee osteoartrose, TKA, arthroplasty, MRI, CT, patient specific, matched instruments
knieslijtage, totale knie prothese, patient specifiek

Sponsors and support

Primary sponsor: Orthopedie, Orbis MC, Sittard-Geleen, the Netherlands
Source(s) of monetary or material Support: Orthopedie, Orbis MC, Sittard-Geleen, the Netherlands

Intervention

Outcome measures

Primary outcome

Biomechanical limb alignment, femoral and tibial component position

Secondary outcome

All patients are operated with PSMI. The operating surgeon reviewed all the pre operative digital plans and had the ability to change the default settings provided from the software. Per operative changes of the approved size of the planned femoral and tibial component are noted if approved pre operative planning changed. Mean operation time (incision to closure in minutes) and blood loss (in ml) will be obtained from the operative record.

Study description

Background summary

Patient specific matched instruments (PSMI) can be used to align total knee arthroplasty. This technique utilizes CT and MR imaging. The present study is designed to investigate postoperative radiographs, pre operative planning and per operative outcome between CT and MRI based PSMI

Study objective

There is no difference between CT- and MRI-based
Patient specific matched instruments for total knee arthroplasty

Study design

Primary outcome, biomechanical limb alignment, femoral and tibial component position were evaluated on 1 year post operative standardized full leg standing radiographs and sagital plane radiographs

Intervention

Patient specific matched instruments (PSMI) for total knee arthroplasty (TKA) is a new and upcoming technique that uses 3D rapid prototyped disposable guides to align the knee prosthesis. This case control study will review a cohort (n= 899 cases) of patients operated for unilateral total knee arthroplasty (TKA) with the use of patient specific matched instruments (PSMI; Signature, Biomet, Warsaw INC). This PSMI utilizes CT or MR imaging. Patients operated for TKA who were not eligible to undergo MRI and were operated by means of CT-based PSMI will be included. These patients will be adequately matched on gender, age and body mass index (BMI) with a group of patients operated with MRI-based PSMI (Control group) out of the cohort.

Contacts

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Eligibility criteria

Inclusion criteria

patients operated for unilateral total knee arthroplasty (TKA) with the use of patient specific matched instruments (PSMI

Exclusion criteria

NA

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2013
Enrollment:	92
Type:	Anticipated

Ethics review

Positive opinion

Date:	19-08-2013
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	NL3956
NTR-old	NTR4122
Other	METC azM/UM / METC Atrium-Orbis-Zuyd : 13N104
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

Accuracy of CT-based patient specific guides for total knee arthroplasty in patients with post-traumatic osteoarthritis and retained metal hardware around the knee joint from previous surgery.
M.G.M. Schotanus, E.H. van Haaren, R.P.M. Hendrickx, E.J.P. Jansen, N.P. Kort
Eur J Orthop Surg Traumatol. 2015 Aug 12