Is there difference of the pre operative planning of the total knee arthroplasty between orthopedic surgeons?

No registrations found.

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

Summary

ID

NL-OMON19968

Source
NTR

Brief title
TKA

Health condition

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).

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

Changes to the plan, the surgeon can modify the settings for femur and tibia alignment.

Secondary outcome

The surgeon is also able to change the size for femur or tibia implant.

Study description

Background summary

To our knowledge, no studies have yet been conducted comparing the pre-operative planning of patients between orthopedic surgeons, experienced with patient specific matched instruments.
This study is designed to address the following research question: is there a significant difference between the alignment of the individual femoral and tibial components as planned.

Study objective

We hypothesise that there would be no significant difference between the preoperative planning between different orthopedic surgeons.

Study design

N/A

Intervention

Fifty cases will be random selected from the total cohort. The planning of these cases will be evaluated by 10 international orthopedic surgeons experienced with patient matched instruments. No patients are involved, only the pre operative plan of patients will be used.

Based on 50 plans for each surgeon, inter observer variability will be calculated

Twenty five cases will be random selected from the total cohort. The planning of these cases will be evaluated by 4 orthopedic surgeons. Each case will be planned for 3 times by each surgeon. Surgeons in Orbis Medisch Centrum will participate in this study. No patients are involved, only the pre operative plan of operated patients will be used.

Based on 3 plans for each case, intra-observer variability will be calculated

Based on 25 plans for each surgeon, inter observer variability will be calculated

Contacts

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Eligibility criteria

Inclusion criteria

Pre operative planned TKA of patients with PSMI

Exclusion criteria

N/A

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	75
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	NL3968
NTR-old	NTR4127
Other	METC Atrium-Orbis-Zuyd : 13N107 and 13N108
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A