

Standscorrectie van het onderbeen door een enkelvoudige laterale gesloten wig (LGW) of een gecombineerde dubbele wig CW), bij slijtage aan de binnenzijde van het kniegewricht.

No registrations found.

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

Summary

ID

NL-OMON21460

Source

NTR

Brief title

Combined wedge osteotomy versus closed wedge osteotomy

Health condition

Medial compartment osteoarthritis

Sponsors and support

Primary sponsor: Afdeling orthopedie, Martini Ziekenhuis Groningen

Source(s) of monetary or material Support: Afdeling orthopedie, Martini Ziekenhuis Groningen

Intervention

Outcome measures

Primary outcome

Primary outcome measure is achievement of an overcorrection of 4 degrees valgus after one year of surgery (HKA angle).

Secondary outcome

Secondary Objectives are to compare these two different HTO techniques regarding radiological scores/ anatomical changes after HTO (Moore-Harvey, Dejour-Bonin, Insall-Salvati and Caton Index). Moreover pain, function scores and quality of life will be compared (VAS and KOOS).

Study description

Background summary

High tibial osteotomy (HTO) is a common procedure to treat symptomatic osteoarthritis of the medial compartment of the knee with varus alignment. This is achieved by overcorrecting the varus alignment to 2-6 degrees of valgus. To achieve this, different HTO techniques are being used. The most common used techniques are medial opening wedge (MOW) and lateral closing wedge (LCW) HTOs. A Cochrane review showed no

evidence whether LCW or MOW is more effective in the treatment of symptomatic medial knee OA, however the LCW is seen as the gold standard. A relatively new technique, the combined valgus producing high tibial osteotomy (CWO), claims to include the advantages of both techniques. This HTO modification avoids metaphyseal tibial bone loss, and decreases the transposition of the tibia condyle and shortening of the patellar tendon after osteotomy even in case of great correction. During the last few years, both the LCW and CWO techniques are commonly used for HTO at the department of Orthopaedics of the Martini Hospital. The clinical results of the CWO technique are very promising. However, until now, there is little scientific evidence on the effectiveness of CWO. Objective of the study: Aim of this prospective randomized trial (RCT) is to compare the gold standard LCW with the CWO in patients eligible for HTO who need a correction of 10 to 16 degrees. Hypothesis is that the CWO technique will achieve more accurate overcorrection of varus malalignment with less anatomical changes of the proximal tibia after 1 year.

Study objective

Aim of this prospective randomized trial (RCT) is to compare the gold standard LCW with the CWO in patients eligible for HTO who need a correction of 10 to 16 degrees. Hypothesis is that the CWO technique will achieve more accurate overcorrection of varus malalignment with less anatomical changes of the proximal tibia after 1 year.

Study design

Preoperatively and 6 weeks, 6 months and one year postoperatively.

Intervention

Patients will undergo a HTO, with either a LCW technique or a CWO technique.

Contacts

Public

Martini Hospital Groningen

Van Swietenplein 1
M.R. Huizinga
Groningen 9728 NT
The Netherlands
+31 (0)50 5245970

Scientific

Martini Hospital Groningen

Van Swietenplein 1
M.R. Huizinga
Groningen 9728 NT
The Netherlands
+31 (0)50 5245970

Eligibility criteria

Inclusion criteria

1. Radiologically confirmed medial compartment osteoarthritis of the knee;
2. Medial joint pain;
3. Varus alignment between 6-12 degrees;
4. An age of 18 and older.

Exclusion criteria

1. Symptomatic osteoarthritis of the lateral compartment;
2. Rheumatoid arthritis;
3. Range of motion of the knee joint less than 100 degrees;
4. Flexion contracture more than 10 degrees.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-04-2013
Enrollment:	110
Type:	Anticipated

Ethics review

Positive opinion	
Date:	12-03-2013
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	NL3735
NTR-old	NTR3898
Other	METC : 43154.099.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A