Combined wedge osteotomy (CWO versus lateral closed wedge osteotomie (LCW) in medial compartment osteoarthritis of the knee

Published: 27-03-2013
Last updated: 23-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Joint disorders
Study type	Interventional

Summary

ID

NL-OMON38706

Source
ToetsingOnline

Brief title
Combined wedge osteotomy versus closed wedge osteotomy

Condition

- Joint disorders

Synonym
jointwear, osteoarthritis

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis

Source(s) of monetary or material Support: geen extrakosten naast normale kosten van valgiserede tibiakoposteotomie

Intervention

Keyword: HTO (higher tibial osteotomy), Knee, osteoarthritis, Osteotomy

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.

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

Randomized Controlled Trial.

Intervention

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

Study burden and risks

There are no extra operative risk factors compared to usual treatment. Possible benefits for the group of patients undergoing CWO could be less/no need for reoperation concerning implant removal, less risk for change of posterior tibial slope.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- radiologically confirmed medial compartment osteoarthritis of the knee
- medial joint pain;
- varus alignment between 6-12 degrees;
- an age of 18 and older.

Exclusion criteria

- symptomatic osteoarthritis of the lateral compartment;
- rheumatoid arthritis;
- range of motion of the knee joint less than 100 degrees;
- flexion contracture more than 10 degrees;
- grade 3 collateral laxity (Insall);
- history of fracture or previous open operation of the lower extremity;
- mental incapacity;
- inability to fill in the questionnaires in Dutch.

Study design

Design

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

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-06-2013
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	27-03-2013
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
Other	Nederlands trial register, nummer volgt
CCMO	NL43154.099.13