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.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21460

Bron
NTR

Verkorte titel
Combined wedge osteotomy versus closed wedge osteotomy

Aandoening

Medial compartment osteoarthritis

Ondersteuning

Primaire sponsor: Afdeling orthopedie, Martini Ziekenhuis Groningen
Overige ondersteuning: Afdeling orthopedie, Martini Ziekenhuis Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2013
Aantal proefpersonen:	110
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	12-03-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3735
NTR-old	NTR3898
Ander register	METC : 43154.099.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A