

Midterm results open versus closed wedge high tibial osteotomy: a follow-up study

Published: 15-03-2012

Last updated: 30-04-2024

Our primary objective is to compare the midterm clinical and radiographic results (6 to 8 years) of CWO versus OWO with a locked plate fixation in the management of patients with medial knee OA and a varus leg alignment with a prospective follow-up...

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

Summary

ID

NL-OMON35361

Source

ToetsingOnline

Brief title

open vs closed tibial osteotomy

Condition

- Joint disorders
- Bone and joint therapeutic procedures

Synonym

standcorrection, valgus osteotomy

Research involving

Human

Sponsors and support

Primary sponsor: Rijnstate Ziekenhuis

Source(s) of monetary or material Support: Eigen onderzoeksfonds

Intervention

Keyword: closed, midterm, open, osteotomy

Outcome measures

Primary outcome

Our primary objective is to compare the midterm clinical and radiographic results (6 to 8 years) of CWO versus OWO with a locked plate fixation in the management of patients with medial knee OA and a varus leg alignment with a prospective follow-up study (of a previous RCT conducted by Gaasbeek et al.: CMO number 2002/181). The primary result is the survival rate at 5 year with as endpoints conversion to TKA or UKA and re-operation.

Secondary outcome

Visual Analogue Scale pain, VAS satisfaction, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Knee Society Score (KSS) and complications

Radiographic evaluation:

Radiographs of varus leg alignment (loss of correction), of OA of the knee on AP and lateral views radiographs, Caton's index (CI) and tibial slope on true lateral radiograph views in 30gr of flexion.

Study description

Background summary

Knee osteoarthritis (OA) is one of the most common joint disorders and is a major cause of knee pain and immobility. Treatment can be non-operative or

operative. In young patients it is desirable to delay primary arthroplasty. Osteoarthritis of the knee is more frequently located in the medial compartment. Patients with OA of the medial compartment often have varus malalignment and this causes an overload of the medial compartment. In order to unload the medial compartment, valgus high tibial osteotomy is the treatment of choice for the young and active patient. Either a closed wedge osteotomy (CWO), or an open wedge osteotomy (OWO) can be performed. Closed wedge osteotomy is the conventional approach that was used for varus gonarthrosis. OWO has become popular more recently. Each option has individual advantages and complications. Between 2003 and 2005, we performed a randomized clinical trial in which we compared CWO and OWO (CMO-nr 2002/181) in 50 patients. A follow-up study is needed to evaluate the midterm results of this cohort.

Study objective

Our primary objective is to compare the midterm clinical and radiographic results (6 to 8 years) of CWO versus OWO with a locked plate fixation in the management of patients with medial knee OA and a varus leg alignment with a prospective follow-up study (of a previous RCT conducted by Gaasbeek et al.: CMO number 2002/181).

Study design

A multicentre prospective study.

Study burden and risks

The extra burden associated with participation in this study are radiographs of the knee and standing whole leg alignment X-rays. Patients are invited to visit the clinic once for the radiographs. The Visual Analogue Scale pain and satisfaction, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Knee Society Score (KSS) are scored.

Contacts

Public

Rijnstate Ziekenhuis

Wagnerlaan 55
6800 TA Arnhem
NL

Scientific

Rijnstate Ziekenhuis

Wagnerlaan 55
6800 TA Arnhem
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients who had a CWO or OWO and participated in the study CMO 2002/181

Exclusion criteria

-

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 02-04-2011
Enrollment: 50
Type: Actual

Ethics review

Approved WMO
Date: 15-03-2012
Application type: First submission
Review commission: CMO regio Arnhem-Nijmegen (Nijmegen)

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	Het wordt aangemeld in het Nederlands Trial register (registratienummer is nog niet bekend).
CCMO	NL38864.091.11