Patient-Specific 3D Guided Correction in High Tibial Osteotomy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
Study type	Interventional

Summary

ID

NL-OMON49330

Source
ToetsingOnline

Brief title
3D Guided HTO

Condition

- Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders)
- Bone and joint therapeutic procedures

Synonym
Leg alignment correction, Osteotomy

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Innovatiefonds Sint Maartenskliniek

Intervention

Keyword: 3D-planning, 3D-printing, Osteotomy, Surgical aid

Outcome measures

Primary outcome

The primary endpoint is the number of outliers defined as > 3 degrees difference between planned and achieved correction angle in frontal plane from 3D CT model.

Secondary outcome

The secondary endpoints will be the difference between planned correction angle (frontal and sagittal) calculated from X-rays and from 3D CT modeling. And the sum of costs of 1 CT-scan, 3D planning and printing, additional surgical costs (sterilization unit) and operative times as recorded in the electronic patient record for using patient-specific cutting guides.

Study description

Background summary

The use of patient specific cutting guides with high tibial osteotomy is thought to achieve a higher accuracy of the planned correction compared to the conventional osteotomy planning and surgical technique. The achieved accuracy of the conventional osteotomy depends greatly on the experience of the surgeon to plan the correction pre-operatively and carry out this correction during the operation. Using a CT-scan to plan the tibial correction automatically and subsequently using 3D-printed cutting guides during the operation removes this dependence on the skill-level of the surgeon. This study aims to investigate the effect of this new technique on the accuracy of correction during a high tibial osteotomy.

Study objective

The primary objective is to investigate whether the use of patient-specific

cutting guides for an open wedge high tibial osteotomy (HTO) provide a more accurate correction relative to the preoperative planning compared to the conventional osteotomy method.

The secondary objective evaluates the difference between the CT-based model planning compared to the conventional planning method performed by surgeons on full-leg X-rays. Furthermore, the costs of the radiology department (CT-scan), 3D planning and printing, surgical costs (sterilization unit) and operative time in using patient-specific cutting guides versus conventional osteotomy surgery will be compared between the two methods.

Study design

This is a prospective single-blinded randomized controlled study, where the patients will be blinded for the use of the 3D planned and printed saw guide.

Intervention

In the intervention group a patient-specific cutting guide will be used to assist positioning and angle of the saw cut, and provide guidance on the degree of angular correction from the pre-operative plan. In the control group the conventional surgical osteotomy technique, without a patient-specific cutting guide will be used.

For all study patients both a full-leg radiograph as well as a CT-scan will be made. The former will be used to perform the standard practice osteotomy planning, while the latter will be used to automatically calculate the planned correction angle. Post-operatively, all patients will receive another CT-scan to determine the achieved correction.

Study burden and risks

Patients will undergo a pre- and postoperative CT-scan (integrated in regular care, which means combined with a regular visit to clinic) of the affected leg additionally to standard care. Other pre-, per- and postoperative care are identical between the two groups and identical to regular care.

The radiation load from the CT is calculated by our radiology expert and estimated at 0.82 mSv per scan (1,64 mSv total). This extra radiation load leads therefore to a slight increased risk. According to the publication ICRP 62 *Radiological Protection in Biomedical Research*, this is justified because this study will lead to acquisition of knowledge, directly aimed at cure of disease.

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

- Medial overload as a result of a varus tibial deformity (MPTA <88 degrees) or medial osteoarthrosis and an MPTA <90 degrees
- Age between 18 to 65 (male) or 60 (female) years
- Consenting to an osteotomy around the knee

Exclusion criteria

- AP (anterior-posterior) instability as a result of ACL / PCL (anterior/posterior cruciate ligaments) deficiency with an indication for reconstruction
- Significant MCL (medial collateral ligament) instability (grade 3)

- Obesity (BMI > 35)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-01-2021
Enrollment:	56
Type:	Actual

Medical products/devices used

Generic name:	Patient-specific cutting guides for high tibial osteotomy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-07-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	22-12-2020
Application type:	Amendment
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
CCMO	NL72556.091.20