BIOPRO resurfacing endoprosthesis versus Keller resection arthroplasty for symptomatic hallux rigidus patients

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The goal of this prospective, randomised controlled trial is to compare outcomes after a BIOPRO® hemi prosthesis or a modified Keller resection arthroplasty for the treatment of hsymptomatic hallux rigidus patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON30275

Source
ToetsingOnline

Brief title
BIOPRO hemi prosthesis for hallux rigidus patients

Condition

- Bone and joint therapeutic procedures

Synonym
hallux limitus, osteoartritis of the big toe

Research involving
Human

Sponsors and support

Primary sponsor: Maaslandziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: BIOPRO hemi prothesis, Hallux rigidus, Keller resection arthroplasty, randomised clinical trial

Outcome measures

Primary outcome

Patient satisfaction, pain, function, AOFAS score, FAOS questionnaire,

radiographic evaluation, complications.

Secondary outcome

n.a.

Study description

Background summary

Hallux rigidus is characterized by a rigid and often painful first metatarsophalangeal (FMTP) joint due to degenerative changes within the joint. Widely used surgical procedures for the management of hallux rigidus are cheilectomy, Keller resection arthroplasty, arthrodesis of the FMTP joint and a prosthesis. With total joint replacement, pain can be reduced and function can be restored. However, many complications, such as waer, osteolysis, foreign body reaction and loosening or displacement of the components, are seen due to great (shear) forces during gait.
The BIOPRO® resurfacing endoprosthesis has been used for many years now, but because of lack of prospective, randomised controlled trials describing outcomes after metallic hemi prosthesis of the proximal phalanx, this study is designed.

Study objective

The goal of this prospective, randomised controlled trial is to compare outcomes after a BIOPRO® hemi prosthesis or a modified Keller resection arthroplasty for the treatment of hsymptomatic hallux rigidus patients.

Study design

The patients included in this study will be selected at random to one of the two groups. One group will be treated with a BIOPRO® hemi prosthesis, the other

group will be treated by a Keller procedure.

Intervention

Operative treatment with either a BIOPRO® hemi prosthesis or a Keller resection arthroplasty.

Study burden and risks

Patients have the same risks and burden compared to patients not included in the study, except for the questionnaire during pre- and postoperative visits.

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

1) hallux rigidus
2) painful FMTP joint

Exclusion criteria

1) hallux valgus or hallux valgus et rigidus
2) patients suffering rheumatoid arthritis
3) (previous) FMTP joint infection
4) severe neurovascular compromised patients
5) metatarsalgia

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):	01-02-2007
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission

Review commission: METC Z: Zuyderland-Zuyd (Heerlen)

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	NL14920.096.06