

‘Lange termijn uitkomst na hallux rigidus ingreep middels Cheilectomie, Keller’s arthroplasty of Arthrodeses’

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27948

Source

Nationaal Trial Register

Brief title

MTP-1 artrose

Health condition

Osteoarthritis (OA) of the first metatarsophalangeal (MTP1) joint, also known as hallux rigidus (HR)

Sponsors and support

Primary sponsor: n.a.

Source(s) of monetary or material Support: n.a.

Intervention

Outcome measures

Primary outcome

The primary outcome of this FU study will be the clinical outcome of treatment for HR measured with the modified AOFAS-HMI scale and Visual Analogue Score for Pain.

Secondary outcome

The secondary outcome includes patient reported satisfactory and outcome measured with the SF-36, MOXFQ and FJS questionnaires and dynamic plantar pressures. Patients dissatisfactory will be defined as less than 9 points in total on the three five-points satisfactory questions in the general questionnaire. As outcome for the plantar pressure analyses, both peak pressures and pressure-time integrals will be used. Recurrence of HR is defined as a comparable or increase in grade of HR, determined based on the Regnauld's score.

Study description

Background summary

Despite the extensive literature on the surgical treatment of HR, no studies with a follow up exceeding 10 years are available. Pain might be one of the main reasons to treat the first ray in patients with HR, but in the long-term creating a permanent satisfactory correction resulting in a restoration of the weight bearing function of the first ray is indispensable. Therefore, this study will be conducted to assess patient satisfactory, clinical and subjective patient reported outcome and plantar pressure after surgical treatment for HR.

Study objective

We hypothesize that, in line with the results of the previous study, cheilectomy and Keller's arthroplasty show better clinical and subjective outcome in patients treated for low grade HR compared to arthrodesis. In addition, we hypothesize that clinical and subjective outcomes are comparable for high grade HR treated with Keller's arthroplasty or arthrodesis after >17 years of FU. Concerning plantar pressure, we expect that cheilectomy restores the weightbearing function of the first ray, while a shift of load to the lesser metatarsals will be observed in the arthrodesis and Keller's arthroplasty group. Concerning recurrence rate, we expect a high recurrence rate in cheilectomy patients compared to Keller's arthroplasty patients, while fusion is achieved in >90% of the arthrodesis patients.

Study design

+/- 17 year postoperative

Intervention

Ninety four feet in 77 patients were included in the primary study and were treated with a cheilectomy (n=32), a Keller's arthroplasty (n=28) and arthrodesis (n=34).

Contacts

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Eligibility criteria

Inclusion criteria

Patients who had participated in the previous study.

Exclusion criteria

Patients who do not want to contribute or were lost to follow up will be excluded from FU.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Other
Start date (anticipated): 01-08-2017
Enrollment: 77
Type: Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 21-06-2017
Application type: First submission

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
NTR-new	NL6261
NTR-old	NTR6435
Other	Z2017012 : 17-T-09

Study results

Summary results

Foot Ankle Int. 2016 Jul;37(7):687-95. doi: 10.1177/1071100716639574. Epub 2016 Mar 23.
Long-term Follow-up of a Randomized Controlled Trial Comparing Scarf to Chevron
Osteotomy in Hallux Valgus Correction.

Jeuken RM, Schotanus MG, Kort NP, Deenik A, Jong B, Hendrickx RP