

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

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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...

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27948

Bron

NTR

Verkorte titel

MTP-1 artrose

Aandoening

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

Ondersteuning

Primaire sponsor: n.a.

Overige ondersteuning: n.a.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

+/- 17 year postoperative

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients who had participated in the previous study.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland
Status: Anders
(Verwachte) startdatum: 01-08-2017
Aantal proefpersonen: 77
Type: Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies
Datum: 21-06-2017
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	NL6261
NTR-old	NTR6435
Ander register	Z2017012 : 17-T-09

Resultaten

Samenvatting resultaten

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