

Lange termijn resultaten na een enkelartrodese

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Patients that have had an ankle arthrodesis will develop arthritis in the adjacent joints after the ankle arthrodesis

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23848

Bron

NTR

Aandoening

ankle arthrodesis, arthritis, artrodese, arthrodesse, enkel, artrose

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Department of Orthopaedics

Overige ondersteuning: Internal funding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Degree of arthritis in the adjacent joints (subtalar joint and talonavicular joint) in patients that have had an ankle arthrodesis

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In patients with end-stage ankle arthritis, an ankle arthrodesis is a common surgical procedure for pain relief. Due to changed biomechanical loading after an ankle arthrodesis, patients might be at increased risk of adjacent joint degeneration. However, the long term effects of an ankle arthrodesis are still largely unknown.

Objective: The main aim of this study is to investigate if patients that received an ankle arthrodesis, have arthritis in the adjacent joints (subtalar joint and talonavicular joint). Furthermore, we would like to study (1) the amount of increase of arthritis in the adjacent joints compared to before surgery, (2) the degree of arthritis in the contralateral ankle, (3) the correlation between degree of arthritis and patient reported outcomes.

Study design: Observational study

Study population: Patients that underwent an ankle arthrodesis in the Erasmus MC at the department of Orthopaedics since 1-1-2004 until 31-12-2016.

Main study parameters/endpoints: The main study outcome is the degree of arthritis in the subtalar joint and talonavicular joint, scored with the Kellgren and Lawrence score based on a CAT-scan.

Doel van het onderzoek

Patients that have had an ankle arthrodesis will develop arthritis in the adjacent joints after the ankle arthrodesis

Onderzoeksopzet

Patients will be invited to visit the Erasmus MC for one follow-up appointment. The time between the ankle arthrodesis and follow-up appointment will vary from 2 to 15 years.

Onderzoeksproduct en/of interventie

This is an observational study in which patients that have had an ankle arthrodesis will be asked to visit the Erasmus MC for a follow-up visit. During this follow-up visit a bilateral CAT-scan of the ankle and an X-ray will be made. Also patients will be asked to fill out questionnaires and will be physically checked by Orthopedic surgeon.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Received a primary ankle arthrodesis at the department of Orthopaedics of the Erasmus MC between 1-1-2004 until 31-12-2016
- A pre-operative CAT-scan of the operated ankle is available

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Received a double or triple arthrodesis
- Arthrodesis with an intramedullary nail or external fixator
- Amputation of the ankle after the arthrodesis
- Patient deceased

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	11-10-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46392
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7331
NTR-old	NTR7547
CCMO	NL65370.078.18
OMON	NL-OMON46392

Resultaten