

The efficacy of flexor tenotomy on the prevention of recurrent diabetic foot ulcers: a randomized controlled trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON50013

Source

ToetsingOnline

Brief title

Flexor tenotomy and ulcer recurrence

Condition

- Diabetic complications
- Soft tissue therapeutic procedures

Synonym

diabetic sores, Diabetic ulcers

Research involving

Human

Sponsors and support

Primary sponsor: Amsterdam UMC

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

Intervention

Keyword: Diabetes complications, Foot ulcer, Tenotomy

Outcome measures

Primary outcome

Ulcer recurrence of the toe, adjacent toe or metatarsal heads after one year of follow-up.

Secondary outcome

Changes in distal interphalangeal joint, proximal interphalangeal joint and metatarsophalangeal joint angles before and after flexor tenotomy in a weight-bearing and non-weight-bearing position, barefoot pressure pattern before and after flexor tenotomy, quality of life at inclusion and follow-up and cost-effectiveness.

Study description

Background summary

Foot ulcers are a frequent problem in patients with diabetes mellitus and can lead to amputations. Prevention of these ulcers is therefore of paramount importance. Hammer/claw toe deformity is commonly seen in patients with diabetes. These deformities increase the risk of ulcer development specifically at the (tip of) the toe. Flexor tenotomy can be used to treat the consequences of hammer toe deformity with the goal to prevent ulcer recurrence. For indication and assessment of outcomes of flexor tenotomy, weight-bearing CT and barefoot plantar pressure measurement can be used.

Study objective

The main objective is to assess the efficacy of flexor tenotomy on the prevention of recurrence of toe ulcers in people with diabetes and a history of toe ulceration. Additionally, we aim to compare interphalangeal joints (IPJ) and metatarsal phalangeal joint (MTPJ) angles in a weight-bearing and non-weight-bearing position, bare-foot pressure and quality of life before and

after the intervention and between study groups.

Study design

A mono-center investigator blinded randomized controlled trial (RCT).

Intervention

A flexor tenotomy of toes with a claw or hammer toe deformity (intervention) versus control group (standard of care including orthosis and shoe offloading).

Study burden and risks

The patients participating in this study will receive routine care, however half of the subjects will receive a surgical treatment that in retrospective cohorts has shown to reduce foot ulcer incidence. For research purposes, additional weight-bearing and non-weight-bearing CT-scans will be obtained for each patient. This project will yield a wealth of information on the applicability and added value of flexor tenotomy. Results of the randomized controlled trial will aid in decision-making while treating diabetic ulcers. Results of functional image acquisition and analysis may facilitate treating physicians in whether for example orthopedic surgery is indicated, if personal modified soles need to be created and if the use of soles actually result in the intended position changes of the foot.

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

- A minimum age of 18 years
- Sufficient understanding of Dutch/English language
- Capable of filling out informed consent
- Peripheral polyneuropathy
- Diabetes mellitus type 1 or 2
- Claw and/or hammer toe deformity
- A documented history of diabetic ulcers underneath the tip of the toe

Exclusion criteria

- No written informed consent
- Not meeting the inclusion criteria
- Open ulcers on the toes
- Previous participation in the study
- Pregnant women
- Concomitant participation in a study in which the patient is exposed to X-rays

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-03-2022

Enrollment: 66

Type: Actual

Ethics review

Approved WMO

Date: 07-10-2021

Application type: First submission

Review commission: METC Amsterdam UMC

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

CCMO

ID

NL78504.018.21