

# Offloading the diabetic foot: a direct comparison of the total contact cast, bivalved total contact cast and cast shoe

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To assess the efficacy of a TCC, a BTCC and a cast shoe with similar plantar soles on offloading the previous ulcer location in people with DM and peripheral neuropathy.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Diabetic complications
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON44038

### Source

ToetsingOnline

### Brief title

Off-loading the diabetic foot

### Condition

- Diabetic complications
- Central nervous system vascular disorders

### Synonym

diabetic foot ulcer - foot wound

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

**Source(s) of monetary or material Support:** ZGT RVE chirurgie

## Intervention

**Keyword:** Diabetic foot, Offloading, Ulcer

## Outcome measures

### Primary outcome

Dynamic in-shoe plantar peak pressure.

### Secondary outcome

Force-time integral and perceived walking comfort.

## Study description

### Background summary

Diabetes Mellitus (DM) is one of the most common chronic diseases. In these patients chronic non-healing ulcers of the foot are a significant problem. The first line of treatment consists of offloading these ulcers to reduce (peak) pressure at the ulcer location. Casting devices such as the total contact cast (TCC), bivalved TCC, or cast shoes are commonly used offloading treatment devices. However, while between-device variability of the plantar sole is controlled, the effect of these devices on the plantar peak pressure has not been directly investigated.

### Study objective

To assess the efficacy of a TCC, a BTCC and a cast shoe with similar plantar soles on offloading the previous ulcer location in people with DM and peripheral neuropathy.

### Study design

Intervention study with a within-subject design, with one measurement session.

### Intervention

A Total Contact Cast, a Bivalved Total Contact Cast, a cast shoe and a non-modelled cast shoe

### Study burden and risks

There is no direct benefit for the subjects from the study and there will be a slight risk to participate in the study. The burden of the study is mainly determined by the time the measurements will take. The load of the measurements is low.

## Contacts

### Public

Academisch Medisch Centrum

Meibergdreef 9  
Amsterdam 1105 AZ  
NL

### Scientific

Academisch Medisch Centrum

Meibergdreef 9  
Amsterdam 1105 AZ  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

People with diabetes who are at risk for plantar foot ulceration will be included. They must be 18 years or older, must have peripheral neuropathy, an unhealed and/or a healed plantar foot ulcer located at the hallux or metatarsal phalangeal joint (MTP) 1, 2, 3, 4 or 5 that was treated with a casting device or a non-ischemic non-infected plantar foot ulcer that is currently being treated using a casting device. People must also present with one or more foot deformities, including claw/hammer toes, hallux valgus, hallux rigidus, prominent

metatarsal heads, pes cavus, pes planus, rearfoot valgus and/or rearfoot varus.

## Exclusion criteria

People will be excluded if they aren't able to walk a distance of 20 m repeatedly without walking aid. They will also be excluded if the previous ulcer location has been amputated, or they have Charcot deformity, equines foot deformity, treatment for serious medical conditions or injuries other than DM that may interfere with lower limb function (walking).

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 12-10-2015

Enrollment: 16

Type: Actual

## Ethics review

Approved WMO

Date: 31-03-2015

Application type: First submission

Review commission: METC Twente (Enschede)

Approved WMO

Date: 17-11-2015

Application type: Amendment

Review commission: METC Twente (Enschede)

Approved WMO  
Date: 09-06-2016  
Application type: Amendment  
Review commission: METC Twente (Enschede)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

ID: 20430  
Source: Nationaal Trial Register  
Title:

### In other registers

Register	ID
CCMO	NL52480.044.15
OMON	NL-OMON20430