

# Is a more comfortable cast available for diabetic foot wounds? A follow-up cohort study

<b>Submission date</b> 05/12/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 08/12/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/08/2022	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A diabetic foot ulcer (DFU) is often cured and prevented by a cast with off-loading (minimizing or removing weight placed on the foot to help prevent and heal ulcers).

Unfortunately, a cast is a nuisance for a patient, because of its irremovable properties. Because of its' stiffness, patients are not able to walk comfortably.

The newer, non-removable total contact softcast (TCS) is easy in its application and comfortable to walk upon.

Healing in patients given the TCS are compared to a cohort of patients treated with a non-removable total contact cast (TCC).

### Who can participate?

Data from patients who received treatment for a DFU using one of the two types of cast between 2010 and 2017 were included.

### What does the study involve?

Patients treated with a TCC are compared to patients treated with a TCS. Wounds are evaluated weekly at the hospital.

### What are the possible benefits and risks of participating?

None

### Where is the study run from?

The study is run from the Wilhelmina Ziekenhuis Assen and supported by the University Medical Centre of Groningen (Netherlands)

### When is the study starting and how long is it expected to run for?

May 2015 to June 2021

### Who is funding the study?

Investigator initiated and funded

Who is the main contact?  
Dr B.P. Vierhout, Bas.Vierhout@WZA.NL

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Protocol serial number**  
M19.230293, NTR6142

## Study information

**Scientific Title**  
Non-removable total contact cast vs non-removable total contact softcast in diabetic foot ulcers

**Study objectives**  
A total contact softcast (TCS) heals as many diabetic foot ulcers (DFU) when compared to a classic total contact cast (TCC).

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
Approved 29/05/2018, University Medical Ethical Committee of the University Medical Center of Groningen (P.O.Box 30 001, 9700RB Groningen, Netherlands; +31 503614204; metc@umcg.nl), ref: M19.230293

**Study design**  
Observational cohort study

**Primary study design**

Observational

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Diabetic foot ulcer

**Interventions**

Patients with a plantar DFU were treated with a TCC or a TCS and followed for 6 months to evaluate the healing of the DFU.

**Intervention Type**

Device

**Phase**

Not Applicable

**Primary outcome(s)**

Percentage of patients with complete ulcer healing within 6 months after the start of treatment with a cast measured using patient records

**Key secondary outcome(s)**

Time to healing (days) measured using patient records

**Completion date**

01/06/2021

**Eligibility**

**Key inclusion criteria**

1. Diabetic patient
2. Open diabetic foot ulcer
3. Ulcer at the plantar part of the foot
4. Neuropathic ulcer

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Senior

**Sex**

All

**Total final enrolment**

61

**Key exclusion criteria**

1. Diabetic without an ulcer
2. Ischemic ulcer
3. Compliance issues

**Date of first enrolment**

01/01/2010

**Date of final enrolment**

01/01/2018

**Locations****Countries of recruitment**

Netherlands

**Study participating centre**

**Wilhelmina Ziekenhuis Assen**

Europaweg-Zuid 1

Assen

Netherlands

9401RK

**Sponsor information****Organisation**

University Medical Center Groningen

**ROR**

<https://ror.org/03cv38k47>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

ChiCoN BV, chirurgen coöperatie Noord-Nederland

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available upon request from BP Vierhout (bas.vierhout@wza.nl). Data will be available during 2022 to research teams with obvious interest for the techniques used in the publication. Data will remain anonymised.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		10/08/2022	12/08/2022	Yes	No