

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

Submission date 05/12/2021	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/12/2021	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/08/2022	Condition category 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

Clinical Trials Information System (CTIS)

Nil known

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?
Results article		10/08/2022	12/08/2022	Yes	No