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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

Registration date
08/12/2021

Overall study status
Completed

Last Edited
12/08/2022

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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

Primary study design
Observational

Study design

Observational cohort study

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