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Offloading ulcers of the forefoot in patients with diabetes mellitus: a comparison between three removable treatment devices

Submission date
10/09/2014

Recruitment status
No longer recruiting

Registration date
07/10/2014

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
People with diabetes are prone to foot ulcers. This is due to peripheral neuropathy (where slightly higher blood glucose levels have damaged nerves in the foot leading to numbness) and peripheral arterial disease (where fatty deposits have led to narrowing of the arteries and a reduced blood flow to the foot). These foot ulcers are potentially very serious, as they can result in infection and, in the worst cases, amputation. Treating the condition involves relieving the pressure on the foot, commonly known as offloading, and this can be achieved in a number of ways. We are going to compare the performance of three different but commonly used offloading devices: a removable total contact cast boot, a cast shoe, and a prefabricated forefoot offloading shoe.

Who can participate?
Adults aged between 18 and 85, with diabetes and a foot ulcer.

What does the study involve?
Patients are randomly allocated into one of three groups. Those in group 1 are treated with the cast boot. Those in group 2 are treated with a cast shoe. Those in group 3 are treated with a prefabricated forefoot offloading shoe. Their progress is then monitored until their ulcer heals or for up to a maximum of 20 weeks.

What are the possible benefits and risks of participating?
The benefit of the study for the patients participating is that their ulcers are treated with devices commonly used in clinical practice. There are no known risks related to participation, as each of the devices has been tested in everyday practice.

Where is the study run from?
The study is run from several collaborating medical centers in the Netherlands and Germany, with the Hospital Group Twente in Almelo being the lead center. Other participating centers are: Mathias Spital in Rheine, Germany and Hospital Group Twente in Hengelo, Medisch Spectrum Twente in Enschede, and Scheper Hospital in Emmen, in the Netherlands.

When is the study starting and how long is it expected to run for?
November 2004 to July 2014.

Who is funding the study?
Euregio Interreg IIIA program (Germany).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2-EUR-II-2=60

Study information

Scientific Title
The efficacy of removable offloading devices to heal plantar forefoot ulcers in diabetes: a multicenter randomized controlled trial

Acronym
OFFLOAD

Study objectives
1. Percentage of healed plantar forefoot ulcers at 12 weeks is not significantly different between the MABAL cast shoe and the bivalved total contact cast and significantly higher in

both these conditions when compared with the forefoot offloading shoe
2. Percentage of healed plantar forefoot ulcers at 20 weeks is not significantly different between the MABAL cast shoe and the bivalved total contact cast and significantly higher in both these conditions when compared with the forefoot offloading shoe
3. Time to complete healing is not significantly different between the MABAL shoe and the bivalved total contact cast and significantly shorter in both these conditions when compared with the forefoot offloading shoe
4. Peak plantar pressure reduction at the ulcer site compared to the patients own footwear is not significantly different between the MABAL cast shoe and the bivalved total contact cast and significantly larger in both these conditions when compared with the forefoot offloading shoe
5. Daily activity level is not significantly different between the MABAL cast shoe and the forefoot offloading shoe and significantly higher in both these conditions when compared with the bivalved total contact cast
6. Quality of life index is not significantly different between the MABAL cast shoe and the forefoot offloading shoe and significantly higher in both these conditions when compared with the bivalved total contact cast.
7. Complication rate is not significantly different between the MABAL cast shoe and the forefoot offloading shoe and significantly lower in both these conditions when compared with the bivalved total contact cast
8. Total treatment costs are not significantly different between the three conditions

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Comittee Twente, first approval: 08/07/2004, ref. METC/04327.bus
Medical Ethical Comittee Twente, approval of amendment: 17/01/2012, ref. METC/12033.bus

Study design
Randomized controlled trial, parallel design of three study arms

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Diabetes mellitus

Interventions

Participants are randomly allocated into one of the following groups:
1. Total contact cast (bivalved), removable fiberglass cast, custom-made, one application, 20 weeks follow-up
2. MABAL cast shoe, removable fiberglass cast shoe, custom-made, one application, 20 weeks follow-up
3. Forefoot offloading shoe, removable, Rattenhuber Talus II, prefabricated, one application, 20 weeks follow-up

Intervention Type
Device

Phase
Not Applicable

Primary outcome measure
Ulcer healing at 12 weeks. Healing is defined as complete wound closure (i.e. 100% epithelialization) without a need for a dressing and without any drainage present, with the wound remaining closed for at least 4 weeks after initial closure

Secondary outcome measures
1. Ulcer healing at 20 weeks
2. Time to healing of the ulcer
3. Reduction in ulcer size in the first 4 weeks of treatment
4. Peak pressure at the ulcer site in the device
5. Peak pressure reduction at the ulcer site in the device, compared to patients own footwear
6. Cumulative stress at the ulcer site in the device
7. Number of daily foot steps
8. Adherence to treatment
9. Complication rate
10. Quality of life
11. Costs of treatment

Overall study start date
23/11/2004

Completion date
31/07/2014

Eligibility

Key inclusion criteria
1. Age >18 and <85 years old
2. Type 1 or 2 diabetes mellitus with HbA1c < 12%
3. Presence of a full thickness (i.e. extending through the dermis) neuropathic ulcer on the plantar forefoot (including the toes), ranging in size between 0.25 cm^2 and 25 cm^2 post debridement, which has been present for at least 2 weeks and is classified as University of Texas grade 1A or 2A
4. Peripheral neuropathy, defined according to the Diabetic Foot Ulcer Classification System for Research Purposes (PEDIS) from the International Working Group on the Diabetic Foot (IWGDF)
5. Wound bed free of all necrotic and infected soft and bony tissue as determined by clinical examination. X-ray films or semi-quantitative culture of the wound, if deemed necessary, will be

performed
6. Ability and willingness to cooperate with the requirements of the study (e.g. able to speak, read and write German or Dutch, have home telephone, remain in the study area for 16 weeks, expect to be available for adverse event monitoring for the duration of the study, consent to randomization and offloading device provision)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Known or suspected disease of the immune system
2. Systemic diseases, such as active rheumatoid arthritis
3. Current malignancy or connective tissue disease
4. Recent treatment with immunosuppressive or chemotherapeutic agents (< 6 weeks prior to study inclusion)
5. Progressive renal dysfunction (clearing <30ml/min or creatinine level >300 umol/liter) or progressive worsening of renal function in the previous 6 months (> 20% per month) or severe nephrotic syndrome (>3 grams protein loss per day). In each of these conditions renal problems leading to dialysis is to be expected on short term basis
6. Additional ipsilateral ulcer on the plantar surface of the midfoot or heel
7. Presence of necrosis, purulence or sinus tracts in the wound that cannot be removed by debridement.
8. Circulation inadequate for healing in treated extremity, determined by an ankle/brachial pressure index (ABI) <0.8 or a toe systolic blood pressure <40 mmHg.
9. Clinical signs of infection, defined according to the Diabetic Foot Ulcer Classification System for Research Purposes (PEDIS) from the IWGDF
10. Severe foot deformity (i.e. any amputation other than the lesser toes, Charcot neuro-osteoarthropathy or equinus deformity).
11. Inability to walk unaided
12. Parallel participation in another intervention trial.
13. Use of antibiotics at randomization
14. Physical or mental conditions of which the patients own physician feels they are, in the best interest of the patient, an exclusion for participation

Date of first enrolment
23/11/2004

Date of final enrolment
31/07/2014

Locations

Countries of recruitment
Germany

Netherlands

Study participating centre
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Sponsor information

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Sponsor type
Government

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Funder(s)

Funder type
Government

Funder Name
Euregio Interreg IIIA program, project 2-EUR-II-2=60 Diabetes FuB (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results of the differences in cumulative plantar tissue stress between healing and non-healing plantar neuropathic diabetic foot ulcers,	01/03/2018	21/01/2019	Yes	No
Results article	results of the efficacy of removable devices to offload and heal neuropathic plantar forefoot ulcers in people with diabetes,	01/02/2018	21/01/2019	Yes	No