ISRCTN62524796 https://doi.org/10.1186/ISRCTN62524796

Evaluation of lightweight fibreglass heel casts in the management of ulcers of the heel in diabetes

Submission date
28/03/2011

Recruitment status
No longer recruiting

Registration date
28/03/2011

Overall study status
Completed

Last Edited
13/12/2018

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
About 15% of people with diabetes at some stage will develop chronic foot ulcers (long-lasting sores). Only two-thirds will heal without some form of surgery and in about one case in 12 the limb is lost through amputation. The factors which cause ulcers, and which delay their healing, are multiple, and there are no specific treatments to improve outcome. Ulcers which occur on the heel pose a particular problem. Recently, some centres have started to use a soft, lightweight, fibreglass cast which is moulded to the heel of the patient. The cast is cheap to make and takes only minutes to fashion, and is incorporated into the dressings which cover the heel. The early evidence is that this device both increases the rate of healing and (in those who have pain in the heel) reduces discomfort. The aim of this study is to prove the effectiveness of this simple and cheap new device.

Who can participate?
Patients aged 18 or over with type 1 or type 2 diabetes and an ulcer of the heel.

What does the study involve?
Participants are randomly allocated to one of two groups, to either have their heel ulcer managed according to current recommendations, or to also have a lightweight fibreglass heel cast incorporated into the dressing which is applied to their heel. Dressings are replaced at least twice a week, and this is done by their regular nurse or a member of the family according to usual practice. Those who have a heel cast have it replaced as often as is necessary. Both groups are otherwise managed according to recommended guidance. We wish to determine whether the use of the heel cast results in an increased number of heel ulcers being healed by 6 months. Local pain, mood and function are also compared in each group, as well as adverse events and costs.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Nottingham Clinical Trials Unit (UK)

When is the study starting and how long is it expected to run for?
February 2011 to June 2015

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
9299; HTA 09/01/53

Study information

Scientific Title
Evaluation of lightweight fibreglass heel casts in the management of ulcers of the heel in diabetes: a randomised controlled trial

Acronym
DRN 528

Study objectives
About 15% of all people with diabetes get foot ulcers and is the source of considerable cost and suffering. Heel ulcers present particular difficulties and may take up to three times as long to heal than ulcers elswehere on the foot even if they do heal. Heel ulcers in diabetes also differ from ulcers elsewhere on the foot in that they are frequently painful. There are currently no specific interventions which have been shown to improve the outcome. However a small number

of specialists in UK have recently started to use lightweight, fibreglass heel casts and there is uncontrolled observational evidence that these devices result in both a reduced time to healing and a prompt improvement in pain and discomfort. The mechanism for any positive effect is not known but may relate to the reduction of shearing and stretching forces applied to the surface of the ulcer. These heel casts take approximately 15 minutes to make and can be easily fashioned in a domiciliary setting. They are applied over the primary wound dressing, and held in place with an outer dressing, being saved and reused each time the dressing is changed. They are replaced when stained, damaged or lost, and can often be worn inside shoes. Health care professionals can be trained in their use in approximately 30 minutes, and the material cost of each cast is approximately £7. Casts need to be replaced on average each three weeks. The purpose of the proposed study is to confirm the effectiveness and cost implications of this simple intervention, by randomly allocating patients with diabetes and ulcers of the heel either to standard care (according to best practice) or standard care and a fibreglass heel cup. The primary outcome will be the proportion of patients with healed ulcers after 24 weeks.

Further details can be found at: http://www.nets.nihr.ac.uk/projects/hta/090153
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0010/53110/PRO-09-01-53.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds West Research Ethics Committee, 16/02/2011, ref: 10/H1307/124

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Diabetes Research Network; Subtopic: Both; Disease: Diabetic foot

Interventions
Heel cast, fibreglass heel casts in the management of ulcers of the heel in diabetes; control (usual care) versus usual care with the addition of a fibreglass heel cast.

Total study duration is 60 months, follow-up is 12 and 24 weeks (post healing). Single Randomisation only

Intervention Type
Other

Phase
Phase III

Primary outcome(s)

Percentage of all ulcers healed at 24 weeks (6 months)

Key secondary outcome(s))
1. Ulcer-related outcomes - Time to healing, change in ulcer area, adverse events (including infection, major and minor amputation) and ulcer recurrence
2. Patient-related outcomes - Local pain (visual analogue scale), mood and function (EQ-5D), Cardiff Wound Impact Schedule (CWIS) and survival
3. Health economic analysis

Completion date
30/06/2015

Eligibility

Key inclusion criteria
1. Type 1 or type 2 diabetes mellitus
2. Age 18 years or over
3. An ulcer of the heel (below the malleoli and affecting the skin overlying the calcaneum) of national pressure ulcer advisory panel-european pressure ulcer advisory panel (NPUAPEPUAP) Grade 24, which has been present for two or more weeks. If there is more than one heel ulcer, one will be selected as the index ulcer and this will be generally the largest or the most clinically significant.
4. Subjects who are both able and willing to give written informed consent
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Frailty or disability which would mean that participation in the study might have an adverse effect of patient well being and mood
2. The need for any offloading device to be nonremovable
3. The likelihood of protocol violation because of planned travel
4. Pregnancy or the possibility of pregnancy
5. Those who withhold consent
6. Active participation in another study of a wound care product
7. The use of topical negative pressure or application of larvae to the index heel ulcer

Date of first enrolment
01/02/2011

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Nottingham Clinical Trials Unit
Nottingham
United Kingdom
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Sponsor information

Organisation
Nottingham University Hospitals NHS Trust (UK)

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme, Grant Codes: 09/01/53

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2017		Yes	No
Protocol article	protocol	26/11/2014		Yes	No