

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/03/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/12/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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?
Vivienne Savage
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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
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 elsewhere 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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 measure

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

Secondary outcome measures

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

Overall study start date

01/02/2011

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 2/4, 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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 529; UK Sample Size: 529

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**

England

United Kingdom

Study participating centre

Nottingham Clinical Trials Unit

Nottingham

United Kingdom

NG7 2UH

Sponsor information**Organisation**

Nottingham University Hospitals NHS Trust (UK)

Sponsor details

Hucknall Road
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Sponsor type

Hospital/treatment centre

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, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

01/02/2017

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?
Protocol article	protocol	26/11/2014		Yes	No
Results article	results	01/05/2017		Yes	No