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A study to explore the benefits of electrical stimulation with the Accel-Heal device on patients with painful venous leg ulcers

Submission date 09/02/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 15/02/2021	**Overall study status** Stopped	
Last Edited 10/10/2023	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Nearly 2 out of every 100 people in the UK has the misfortune to develop a venous leg ulcer. This happens because disease in the blood vessels in the lower parts of the leg makes blood collect which leads to swelling, reduced oxygen and eventually an ulcer. It is already known that wrapping a compressing bandage around the leg is proven to be the most effective treatment and if this happens many ulcers will heal.

Unfortunately, venous leg ulcers are often painful and in many cases this makes patients reluctant to accept a compressing bandage which means their ulcers will take much longer to heal. Pain killing medicine can be used, but often these drugs don't work well on ulcer pain. The purpose of this study is to test whether a small, disposable device called Accel-Heal® which applies a tiny electric current to the ulcer, can reduce the pain and allow more patients to accept compressing bandages. Patients can't feel the electric current. Patients will wear the devices for a total of 12 days and keep a diary of how much pain they were feeling, what medicines they have taken and whether they were able to wear the compressing bandages.

Who can participate?
Patients aged 18 years or above, with leg ulcers that meet the inclusion cirteria.

What does the study involve?
Forty patients will be asked to join the study by adult community nursing teams in Yorkshire and Northumbria. In order to carry out a fair test, half of the patients will be chosen by chance to wear the real device, whilst half of the patients will wear a dummy device that looks the same but gives no electric current. This study is a small-scale version of a future larger study to check whether the design is correct.

What are the possible benefits and risks of participating?
It is not anticipated that there will be a safety risk to any of the patients in this study from Accel-Heal. Accel-Heal has been on the UK market since 2008, during which time there have not been any serious harm associated with the device. If the active Accel-Heal devices are able to reduce

pain, it will be of an immediate benefit to the patients in the study: it may reduce the amount of pain medicine they are taking and may enable patients to tolerate compression bandaging which known to be an effective therapy for this type of ulcer.

Where is the study run from?
Mid Yorkshire Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
November 2019 to September 2022

Who is funding the study?
Accel-Heal Technologies Ltd (UK)

Who is the main contact?
Dr Leanne Atkin, leanne.atkin1@nhs.net
Dr Robin Martin, robin@robinmartinphd.com

Contact information

Type(s)
Scientific

Contact name
Dr Robin Martin

ORCID ID
https://orcid.org/0000-0002-9314-0437

Contact details
3 Manor Farm Barns
Foggathorpe
Selby
United Kingdom
YO8 6PZ
+44 (0)7736736752
robin@robinmartinphd.com

Type(s)
Public

Contact name
Dr Robin Martin

ORCID ID
https://orcid.org/0000-0002-9314-0437

Contact details
3 Manor Farm Barns
Foggathorpe
Selby
United Kingdom

YO8 6PZ
+44 (0)7736736752
robin@robinmartinphd.com

Type(s)
Scientific

Contact name
Dr Leanne Atkin

ORCID ID
https://orcid.org/0000-0002-4830-1967

Contact details
University of Huddersfield
Huddersfield
United Kingdom
HD1 3DH
+44 (0)1484 472905
leanne.atkin1@nhs.net

Additional identifiers

Integrated Research Application System (IRAS)
279505

Protocol serial number
AH-1 2019

Study information

Scientific Title
A pilot randomised controlled trial exploring the effects of the Accel-Heal electrical stimulation device in VLU patients reporting significant pain.

Study objectives
The overall objective is to pilot the study design for a future RCT assessing the ability of the Accel-Heal electrical stimulation device to reduce pain in venous leg ulcer patients so that they remain in concordance with their prescribed compression therapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design

Multicenter interventional pilot randomised control trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Reduction of pain in patients with venous leg ulcers so that they will adhere to compression bandaging

Interventions
Patients with painful venous leg ulcers will be randomised between the active sub-sensory electrostimulation device Accel-Heal or a placebo device that looks exactly the same. Accel-Heal is a low-voltage biphasic and monophasic pulsedcurrent (LVBMPC) electrical stimulation device consisting of 2 adhesive electrode pads connected to a disposable power unit. Therapy is provided for 12 days as 6 x 2-day units. Accel-Heal is designed to stimulate and promote venous leg ulcer healing using a pattern of subsensory bioelectrical pulses. It is used alongside standard care including compression therapy.

Patients will be randomised using randomised blocks of size 2, using opaque sealed envelopes.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Accel-Heal, UDI 17000545

Primary outcome(s)
Pain measured using the Brief Pain Inventory score recorded each day from baseline to day 14

Key secondary outcome(s)
1. Neuropathic pain score using PainDetect assessment tool each day from baseline to day 14
2. Consumption of analgesics each day from baseline to day 14
3. Number of days without prescribed compression from baseline to day 14measured by self report
4. Number of patients recruited per unit time measured throughout
5. Frequency of patients withdrawing and completing the study measured throughout using patient records
6. Telephone or face-to-face interview about pain; completed at removal of Accel-Heal to discuss how bad the pain was, what patients tried to do about it (or not), how effective their efforts to reduce pain were, pain interference with life, and pain interference with compression therapy. SF-12 score for quality of life (or equivalent) recorded at enrolment, removal of Accel Heal, and end of the 6-week study
7. Ulcer area; measured at enrolment, removal of Accel Heal, and end of the 6-week study
8. Wound bed and peri wound skin; assessed at enrolment, removal of Accel Heal and end of the 6-week study

Completion date
30/09/2022

Reason abandoned (if study stopped)
Study was not started.

Eligibility

Key inclusion criteria
1. Patients with venous ulceration with excluded peripheral arterial disease using ABPI, TBPI or clinical assessment
2. Patients who report significant ulcer pain (above 4 on a 10-point numerical rating scale) despite analgesics
3. Patients who consent to being randomised to receive treatment either with Accel-Heal electrical stimulation in combination with compression therapy, or compression therapy with a non-active placebo Accel-Heal device
4. Patients whose ulcer is not circumferential
5. Patients who have not had their ulcer for more than 12 months
6. Patients whose ulcer area is greater than 1 cm^2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Patients who are under the age of 18 years
2. Patients who are unable to provide informed consent
3. Patients with ulcers of non-venous aetiology
4. Patients whose ulcers are not painful
5. Patients who are not prepared to try to receive effective levels of compression in combination with the Accel Heal electrical stimulation device for 12 days
6. Patients who are unable to undertake regular pain scores and keep a pain diary
7. Patients whose situation means that they cannot themselves or receive from carers a change of Accel-Heal every 2nd day
8. Patients who have had their ulcer for more than 12 months
9. Patients whose ulcer is circumferential
10 Patients whose ulcer area is 1cm^2 or less

Date of first enrolment
01/06/2021

Date of final enrolment
30/05/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Pinderfields Hospital
Mid Yorkshire Hospitals NHS Trust
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
North Tyneside General Hospital
Northumbria Healthcare NHS Foundation Trust
Rake lane
North Shields
United Kingdom
NE29 8NH

Sponsor information

Organisation
Accel-Heal Technologies Ltd.

Funder(s)

Funder type
Industry

Funder Name
Accel-Heal Technologies Ltd

Results and Publications

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date