ISRCTN24438635 https://doi.org/10.1186/ISRCTN24438635

MIST ultrasound therapy compared to UK standard care for the treatment of non-healing venous leg ulcers.

Submission date	Recruitment status	[_] Prospectively registered
29/05/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/08/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
20/04/2018	Circulatory System	

Plain English summary of protocol

Background and study aims
Venous leg ulcers (VLUs) are wounds which are often chronic and difficult to heal. VLUs affect between 1 and 3.2 people per 1000; they cause pain, reduced mobility and impact negatively on patients' quality of life. Standard treatment for patients with VLUs is the application of strong, sustained compression with bandages or stockings. The MIST ultrasound system is a non contact device which delivers low frequency ultrasound through a gentle saline mist directed at a patient's wound. This study aims to determine whether the use of the MIST device used in combination with standard treatments can improve healing of VLUs compared to UK standard practice. It will also show whether the MIST regimen improves participants' quality of life and reduces the incidence of infection.

Who can participate?
Adults (males and females over 18 years old) with venous leg ulcers between 6 weeks and 5 years in duration can participate in this study. Patients with certain underlying diseases which may affect wound healing will be excluded, and those with diabetes must show it is controlled (Hba1c <12%).

What does the study involve?
All study participants will receive four weeks of standard treatment once a week. They will then be randomly allocated to either the active group or the control group to receive a further eight weeks of treatment. Participants in the active group will receive treatment with the MIST device three times a week, combined with standard care (change of compression bandage and dressings) three times a week. The control group will receive UK standard care only (which is dressing and compression bandage change at least once a week). The participants' ulcers will be measured, photographed and assessed once a week. Changes in participants' health related quality of life will be assessed using a questionnaire at the beginning and end of the trial. Wound recurrence rates 90 days after the end of the treatment will be assessed.

What are the possible benefits and risks of participating?
Participants will benefit from regular and consistent treatment by experienced wound healing

nurses and there is some evidence to suggest that treatment with MIST can promote wound healing. Risks to the patients from treatment with the MIST device are very low.

Where is the study run from?
Patients will receive all their treatment at a single research clinic (Wound Healing Research Unit, Cardiff) at the University Hospital of Wales.

When is the study starting and how long is it expected t run for?
We expect to begin recruiting patients in June 2012 and finish recruiting in April 2013. The study will run until September 2013.

Who is funding the study?
The study is being funded by the manufacturer of the MIST device, Celleration Inc. (USA)

Who is the main contact?
Dr Judith White
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Study website
http://www.wales.nhs.uk/sites3/page.cfm?orgid=443&pid=62614

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01671748

Secondary identifying numbers

12-SUR-5323

Study information

Scientific Title
Pragmatic randomised controlled trial of MIST ultrasound therapy compared to UK standard care for the treatment of non-healing venous leg ulcers.

Study objectives
Is there a difference in the mean change in wound area between patients with hard-to-heal venous leg ulcers treated with "MIST + standard care" and patients treated with "standard care alone" for 8 weeks?

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Wales Research Ethics Committee, 16/05/2012, ref: 12/WA/0133

Study design
Prospective single-centre pragmatic assessor-blinded randomised controlled trial

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Wound healing, venous leg ulcers

Interventions
All participants will receive standard care (debridement as necessary, dressing change, compressing therpy) once a week for 4 weeks; this is in order to standardise care prior to randomisation.

Intervention:
Application of MIST ultrasound therapy (between 4 and 12 minutes duration, depending on wound area) 3 times a week; combined with standard care 3 times a week (this will comprise debridement as necessary, dressing change and compression therapy change) for 8 weeks.

Comparator:
Standard care once a week (dressing change and compression therapy change) for 8 weeks (if clinically necessary patients will receive dressing/bandage changes more frequently)

Intervention Type
Procedure/Surgery

Primary outcome measure
The percentage and actual (cm2) change in wound area between baseline and exit visits. Wound area will be measured using a digital imaging device which digitally photographs the wound and allows accurate tracing of the wound boundary. A single blinded assessor will perform all tracing and measurements to reduce the risk of bias and improve consistency.

Secondary outcome measures
The change in health related quality of life (HRQoL) between baseline and exit visits. This will be measured using a validated tool, the Cardiff Wound Impact Schedule (CWIS).
This questionnaire consists of three areas:
1. Physical symptoms and daily living
2. Social life
3. Wellbeing. The patient also provides a global HRQoL score and satisfaction with HRQoL.

The number wound infections (as demonstrated by clinical symptoms) suffered by each patient from beginning of treatment (week 5) to end of treatment (week 13).

Wound characteristics including wound condition, exudate, pain frequency, pain severity, and odour. These will be assessed by experienced wound healing researchers.

Proportion of wounds which remain healed 90 days after the end of the study. This outcome will be assessed by a single question phone call (conducted by a research nurse).

Overall study start date
13/08/2012

Completion date
31/10/2013

Eligibility

Key inclusion criteria
1. Venous leg ulcers (as diagnosed by the clinician)
2. Ankle Brachial Pressure Index (ABPI) >0.8
3. If multiple ulcers are present treat largest ulcer only (index ulcer) with minimum distance of 1 cm between index ulcer and any other ulcer
4. Age: 18 years or older
5. Ulcer size: Between 5 cm2 and 100 cm2 (with no longest length being greater than 10 cm) at randomisation point (week 5)
6. Mobility: Ability to attend clinic
7. Index ulcer between 6 weeks and 5 years duration prior to screening date

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Uncontrolled diabetes (Hba1c >=12%) as tested within the past 3 months
2. Index ulcer has active infection on day of inclusion requiring use or oral or IV antibiotics
3. Renal failure
4. Index ulcer has exposed tendons, ligaments, muscle, or bone
5. Osteomyelitis or cellulitis or gangrene in study limb
6. Subjects with amputation above a trans metatarsal amputation (TMA) in the study limb
7. Subjects with active malignancy on the study limb
8. Index ulcer that is of arterial disease aetiology
9. Females of child bearing potential who are not willing to use a method of highly effective contraception during the entire study
10. Planned vascular surgery, angioplasty, or thrombolysis procedures within the study period, or 6 weeks post-operatively
11. Planned surgical procedure during the study period for the index wound
12. Prior skin replacement, negative pressure therapy, ultrasound therapy applied to the index wound 2 weeks before screening
13. Oral or IV antibiotics within 48 hours of baseline measurements
14. Growth factor therapy within previous 14 days of screening date
15. Currently receiving or has received radiation or chemotherapy within 3 months of randomisation
16. Pregnant or breast feeding women
17. Subject is currently enrolled or has been enrolled in the last 30 days in another investigational device or drug trial
18. Subject's wound would require ultrasound near an electronic implant or prosthesis
19. Subjects lacking capacity to provide informed consent

Date of first enrolment
13/08/2012

Date of final enrolment
31/10/2013

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Cedar
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CF14 4UJ

Sponsor information

Organisation
Cardiff and Vale University Health Board (UK)

Sponsor details
Research & Development Office
University Hospital of Wales
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research.development@wales.nhs.uk

Sponsor type
University/education

Website
http://www.cardiffandvaleuhb.wales.nhs.uk/

ROR
https://ror.org/0489f6q08

Funder(s)

Funder type
Industry

Funder Name
Celleration Inc (USA)

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?
Basic results				No	No
Results article	results	01/10/2016		Yes	No