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Wound bed cleaning and preparation using scalpel debridement: a multi-centre randomised controlled trial feasibility study in patients with systemic sclerosis

Submission date
05/01/2022

Recruitment status
No longer recruiting

Registration date
19/01/2022

Overall study status
Completed

Last Edited
01/11/2023

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Scleroderma is a chronic disease that affects the blood circulation, the body's immune system, the skin and internal organs. Approximately 50 % of the patients with scleroderma suffer from ulcers on the fingers and/or toes. These ulcers are caused by poor blood circulation and tightening of the skin. The poor blood circulation damages the skin, while the skin tightening reduces skin's flexibility making it susceptible to damage from stretching or rubbing.
Little is known about what treatments are effective in healing these ulcers. Some research in other disease suggests that using a scalpel to remove debris / dead skin on or surrounding the ulcer(s) might improve healing. Although, in scleroderma related ulcers, there is a lack of studies to support the use of this approach. In addition, rheumatologists disagree regarding its practical use. Therefore, in this application we are proposing to run a small study (feasibility study) which would inform us whether or not removing debris / dead skin from an ulcer has the potential to help healing; and whether or not it is possible to conduct a larger, costlier study (Randomised Controlled Trial) to investigate its effects further.

Who can participate?
Adults over 18 years, diagnosed with scleroderma with at least one digital ulcer

What does the study involve?
Patients will be equally randomised to either a treatment group of scalpel debridement or to a control group receiving traditional wound dressings. During 24 weeks, all patients will be seen by a clinician every 7, 14 or 21 days, as per clinical needs, to receive treatment for their ulcers. The wound-care for the treatment group will be: wound cleaning, topical anesthesia (cream to numb the ulcer), scalpel debridement of the of the wound/s, wound cleaning and dressings. Patients also will receive information regarding wound-care, dressing change and infection. The control group will receive the same treatment with the exception of scalpel debridement. Treatment post-study will continue as per usual care.
Since the aim of the study is assessing the practicalities of running a larger study, one of

outcomes will be to assess patients' willingness in staying in the study. It will also assess the potential effects of scalpel debridement on ulcer healing, by evaluating healing rate (by measuring the wound surface area) and time-to-healing (in days). Further data will be collected on treatment acceptability and effects on quality of life, to evaluate the effects of the treatment from the patient's perspective. The potential costs involved in this treatment will also be evaluated.

What are the possible benefits and risks of participating?
Participants will be contributing to our knowledge about how best to heal digital ulcers in patients with Scleroderma. Our hope is that we can use this knowledge to inform a much larger study. We cannot promise the study will definitely help you as an individual or that your ulcers will heal faster than if you had not taken part; but the information we get from this study will help to answer the question as to whether one of these treatments options is better than the other.
We do not anticipate participants to be at any added risk by taking part in this study. The risks would be the same as those encountered when patients attend for clinic treatment as they usually do (e.g. infection). Being in the study means that participants will be closely monitored and any complications would be identified early on.
All participants involved in the study will experience some additional burden by having to complete some questionnaires and some additional clinic visits. We have designed the study to minimise as much burden on participants by making the questionnaires as short as possible and also relying on data that will be collected by your care team during your appointments.

Where is the study run from?
University of Leeds (UK)

When is the study starting and how long is it expected to run for?
April 2019 to April 2024

Who is funding the study?
National Institute for Health Research (NIHR) (UK).

Who is the main contact?
Dr Begonya Alcacer-Pitarch, b.alcacer-pitarch@leeds.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Begonya Alcacer-Pitarch

ORCID ID
https://orcid.org/0000-0002-2208-444X

Contact details
Leeds Teaching Hospitals NHS Trust
2nd Floor, Chapel Allerton Hospital
Chapeltown Road
Leeds

United Kingdom
LS7 4SA
+44 113 3924879
b.alcacer-pitarch@leeds.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
272506

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 51066, ICA-CL-2018-04-ST2-015, IRAS 272506

Study information

Scientific Title
SHED SSc - SHarp dEbridement of Digital ulcers in Systemic Sclerosis: a multi-centre Randomised Controlled Trial feasibility study

Acronym
SHED SSc

Study objectives
Is it feasible to conduct a study of sharp debridement of digital ulcers in systemic sclerosis?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/12/2021, Yorkshire & The Humber - Bradford Leeds Research Ethics Committee (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 2071048083; bradfordleeds.rec@hra.nhs.uk), ref: 21/YH/0278

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Debridement of digital ulcers in systemic sclerosis

Interventions

The participant will have a baseline clinical examination to assess the number, location and size of all digital ulcers. Ulcer measurements will be taken, either manually using a disposable ruler, by planimetry (working out the size by tracing the outline onto a transparent material with 1 cm2 grid lines), by photo-digital planimetry (computer software will work out the size from a digital photograph) or by High Resolution Ultrasound (this uses ultrasound to look at the ulcer at a microscopic level to accurately determine the size, and is only available at the Leeds site). The largest digital ulcer will be selected by the clinician as the reference ulcer. As is standard practice, if an infection is suspected, a swab will be taken for diagnosis purposes so that antibiotics can be prescribed if necessary.

At the baseline appointment, participants will be asked for their demographic data, to describe their pain on the Numeric Rating Scale and to complete the following questionnaires:

- Manchester Foot Pain and Disability Index (MFPDI)
- Cochin Hand Function Scale (CHFS)
- Systemic Sclerosis Quality of Life questionnaire (SSC Qol)
- Hospital Anxiety and Depression Scale (HADS)
- EQ-5D-5L
- Bespoke health resource use questions: A specific healthcare resource use questionnaire for patients will capture visits to their general practitioner and to specialist services, admissions to hospital, use of medication, and other related medical expenses incurred e.g. private health-care etc. through the length of the trial.

Once the baseline clinical assessment and questionnaires have been completed, the participant will be randomised. There will be equal chance of being assigned to either standard wound-care (control arm), or sharp debridement (removing dead cells with a scalpel blade to prepare the wound bed for new skin cells) plus standard wound-care (intervention arm). Participants will be informed which treatment they have been randomised to receive.

Participants in the control arm will continue to receive standard wound-care treatment (with the exception of pain relief gel/cream and sharp debridement) and have access to all clinical services as normal. Standard treatment usually consists of wound cleaning with saline water, wound dressing, and patient education regarding wound self-care, dressing change and infection checks. Clinic visits will be at intervals of approximately every 7,14, or 21 days as determined by the clinician. If the clinician considers it absolutely necessary on clinical grounds, sharp debridement
can be undertaken during follow-up visits and this treatment will be recorded in a treatment visit log. In these cases, the patient will be classed as withdrawal from treatment, but they will still be included in the analysis in the intervention arm as per intention to treat analysis. They will continue to receive usual treatment care from their clinic.

Participants in the intervention arm will undergo wound cleaning with saline, pain relief gel /cream application and sharp debridement of the DU (removing dead cells with a scalpel blade to prepare the wound bed for new skin cells). This will be repeated at 7-day intervals until the need for sharp debridement reduces. At this point the frequency of appointments will be reduced to between every 14 to 21 days, as per clinical judgment, until the participant is required to receive standard wound-care only. If the clinician thinks it is required, additional debridement will be undertaken
during follow up visits.

For all participants, data will be collected on number of past and current ulcers, number of resolved ulcers, and the appearance of new ulcers at each visit. They will be examined for infection and ulcers. The reference ulcer will be measured using the same method as at baseline. Participants will describe their pain on the Numeric Rating Scale. The treatment received at each visit will be recorded in a treatment visit log, and any adverse events will be reported to the trial management team.

The status of the reference ulcer will be assessed at each visit. If during the study, a participant thinks their reference ulcer has healed, they will be asked (if possible) to take a photograph of the healed area in order to show staff at the next clinic visit. The clinician will confirm healing date at this visit. If the reference ulcer has healed, participants will visit the clinic as per standard care for treatment of any remaining ulcers, but data on these visits/ulcers will not be collected as part of the research. Participants whose only ulcer was their reference ulcer will not need to attend clinic again (unless required as per standard care or need) until their 12 or 24 week post-randomisation research follow-up appointments.

In between clinic visits, all participants will re-dress their ulcers every 2-3 days in line with current practice. For participants or carers, who are unable to change the dressings themselves, arrangements will be made: for those able to attend their GP surgery, arrangements will be made with practice nurses; district nurse appointments will be made for patients with impaired mobility in line with routine practice.

All participants will complete the 12-week post-randomisation follow-up questionnaires, which are the same questionnaires completed at the baseline appointment, and describe their pain on the Numeric Rating Scale. This will be done either during a clinic visit or posted out for return by pre-paid envelope if the participant does not attend. In cases where participants fail to return their questionnaire, they will receive up to two reminders via post (after 2 and 4 weeks) followed by a telephone call if required in order to try and collect some outcome data. This will be repeated at 24 weeks after randomisation. After the final visit, participants will return to usual NHS care.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Study recruitment and the plausibility of achieving the proposed sample size for the full-scale RCT measured by summarising number of patients screened, eligible, consenting and randomised during the 18 month recruitment period
2. Study retention rates measured by proportion of questionnaires completed at week 12 and week 24 post randomisation
3. The willingness of clinicians to randomise participants, and of patients to be randomised measured via compliance recorded on clinician completed treatment logs up to and including week 24 post randomisation
4. Whether intervention delivery is achievable and acceptable to patients and practitioners; measured via clinciain completed treatment logs up to and including week 24 post randomisation
5. To explore any barriers to recruitment and how these might be overcome from the perspective of patients measured via anonymised screening forms
6. To assess the completeness of follow-up to establish how feasible it is to collect patient-reported outcome measures including data related to patient function, health status and adverse events measured at baseline, week 12 and week 24 post randomisation

Key secondary outcome(s))
1. Patient National Health Service (NHS) resource use measured at baseline, week 12 and week 24 post randomisation
2. Health Related Quality of Life (HRQoL) measured via EuroQol five dimensions (EQ-5D-5L) at baseline, week 12 and week 24 post randomisation

Completion date
30/04/2024

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Primary diagnosis of Scleroderma (2013 ACR/EULAR classification criteria)
3. Has at least one current digital ulcer on the fingers or toes (digital ulcer defined as a denuded area with a defined border and loss of epithelialisation or loss of epidermis present on the digits, excluding those over the metacarpophalangeal joints but including ulcers derived from pitting scars (small size hyperkeratosis))
4. Is able to self-complete the English language outcome measure tools (or complete with assistance such as family member or translator);
5. Is willing and able to provide written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
33

Key exclusion criteria
1. Primary diagnosis other than Scleroderma (e.g. other connective tissue disease, rheumatoid arthritis)
2. Digital ulcer derived from calcium deposits or gangrene
3. Patient is due to undergo planned surgery in the hand or foot with the digital ulcer within next 6 months;
4. Is currently participating in any Clinical Trial of an Investigational Medicine or a study in which the intervention will influence ulcer healing (as determined by the site PI)

Date of first enrolment

16/01/2023

Date of final enrolment
30/09/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
St James' S University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
The Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name

NIHR Academy

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon reasonable request from the Chief Investigator (B.Alcacer-Pitarch@leeds.ac.uk) following completion of the trial and publication of trial results. Requests will be considered on a case-by-case basis. Data will be made available for secondary analyses, and only anonymised data will be provided.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No