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Dressing of diabetic foot ulcers; infection deterrent (DRUID)

Submission date 21/01/2019	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 25/01/2019	**Overall study status** Completed	
Last Edited 25/07/2024	**Condition category** Circulatory System	

Plain English summary of protocol

Background and study aims
Diabetic foot ulcers (DFU) can lead to infection and further deterioration to health. They are a considerable burden to both the NHS and the patient. The management of DFUs initially focuses on achieving wound healing. However, in many cases this objective is not met and chronic wound management then shifts its attention to avoiding infection and further complications. Clinicians have the option to treat the wound conservatively (non-antimicrobial dressings) or more aggressively (antimicrobial dressings to actively kill bacteria in the wound). At present there is a lack of data available to aid clinicians in deciding what approach is best. This study will explore if one approach is potentially better than the other in terms of reducing the risk of infection and promoting wound healing.

Who can participate?
Patients aged over 18 with a diabetic foot ulcer

What does the study involve?
Participants are allocated at random to one of the three groups to be treated with either a non-antimicrobial dressing, a rotational regime of three different chemical-based antimicrobial dressings (honey, silver, iodine), or a physical antimicrobial dressing, for 18 weeks or until ulcer healing has been achieved. In addition to recording the need to change wound management due to significant deterioration or improvement, patient and clinician satisfaction are compared, as are infection rates and wound healing outcomes.

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

Where is the study run from?
Cumbria Partnership NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2019 to May 2020

Who is funding the study?
BSN Medical

Who is the main contact?
Dr Leon Jonker
leon.jonker@cumbria.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Leon Jonker

ORCID ID
https://orcid.org/0000-0001-5867-4663

Contact details
Science & Innovation Manager
Cumbria Partnership NHS Foundation Trust
E27 Ruskin Corridor
The Carleton Clinic
Cumwhinton Drive
Carlisle
United Kingdom
CA1 3SX
+44 (0)176824 5975
leon.jonker@nihr.ac.uk

Additional identifiers

Protocol serial number
39550

Study information

Scientific Title
Investigation of different dressing strategies for diabetic foot ulcers to minimise risk of infection: a prospective, randomised, controlled, feasibility clinical trial

Acronym
DRUID

Study objectives
The aim of this randomised, controlled, prospective pilot trial is to determine and compare the wound healing efficacy of three different dressing regime approaches to DFU management.

These are a) non-antimicrobial dressing, b) a rotational approach with dressings that exert an antimicrobial effect through chemical interaction with bacteria, and c) a dressing that interacts with bacteria through physical interaction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East – Tyne & Wear South Research Ethics Committee, NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, Tel: 0207 1048084, Email: nrescommittee.northeast-tyneandwearsouth@nhs.net, NRES approval 17/12/2018, HRA approval 17/12/2018, REC ref: 18/NE/0330

Study design
Randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetic foot ulcer

Interventions
Following written consent, at week 0, participants are allocated at random to one of the three arms in a 1:1:1 fashion. A randomised sequence from the freeware randomisation programme, see https://www.randomizer.org/ will be used to obtain the randomised list. Since the eligible patients with DFUs have chronic wounds, there is ample time for the patient to decide whether to take part or not, and to allocate a randomisation arm once the patient has provided written informed consent. When the patient has provided written informed consent the treating podiatrist will either phone or e-mail the research department for the next allocation. At this stage the relevant dressing treatment regime will commence. For Arm B (rotation), the order will be Actilite, Urgotul SSD, each for 2 weeks and then same order again beyond week 6. Three different dressing regimes will be applied, and one of these regimes will utilise three different dressings. Therefore, a total of five different dressings will be utilised.

A: Urgotul, active element: TLC (technology lipido-colloid)
B: Actilite, Urgotul SSD, Inadine (2-week rotation in this order), active element: manuka honey, silver, iodine, respectively
C: Cutimed Sorbact, active element: DACC (dialkylcarbamoyl chloride)
A, B, C: Tegaderm Foam Adhesive, secondary dressing for all arms

Participants will be randomised to one of three arms, see Table 1, for 18 weeks or until ulcer healing has been achieved (if the latter occurs then they will still be followed up according to the study schedule). All participants will have demographic data obtained and a number of baseline and follow-up measures, see Table 2. In total, patients will be in the trial for 26 weeks.

Intervention Type
Other

Primary outcome(s)
The bioburden in the index DFU, as measured by microbiological diagnostics at week 0, 6, 12, 18. The bacterial load will be quantified using the following formula: bacterial load (CFU/g) = (number of CFUs on plate ×103) / dilution. This will be performed for aerobic and anaerobic cultures. Any change at follow-up versus week 0 baseline figure will be calculated. In addition identify bacterial species and test antibiotic sensitivity. The bacterial species will be identified by standard microbiological techniques, including gram stain and microscopic examination, and trial specimen samples will be processed and analysed in the same microbiology laboratory where regular samples are sent, per Trust standard operating procedures. Levine's technique will be applied for swabbing of the wound (Levine et al, 1976). Samples, taken with a sterile cotton swab and placed in containing charcoal transport medium, will be sent to the laboratory asap. Wound swabs should reach the laboratory on the day that they are taken, but in exceptional circumstances can be stored in a specimen fridge overnight. Specimens must not be left over the weekend or bank holidays.

Key secondary outcome(s))
1. Wound size and characteristics, assessed at week 0, 3, 6, 9, 12 and 18:
1.1. Foot ulcer size, measured with Coloplast grid tool (week 0, 3, 6, 9, 12, 18), with week 18 being primary outcome measure.
1.2. Clinical characterisation of wound (incl. erythema, purulence, odour, plus depth)
1.3. PUSH and Texas Diabetes Foot Ulcer clinical severity score
1.4. Wound closure status and incidences of adverse events
1.5. Wound depth
2. Incidence of requirement to deviate from the randomised intervention arm due to significant deterioration or improvement in foot ulcer status, as determined by the treating clinician
3. Microbiological assessment of the diabetic foot ulcer (bacterial count and identification, antibiotic sensitivity) at week 0, 6, 12 and 18
4. Safety of applied dressing regimes (ongoing):
4.1. Wound infection incidence
4.2. Reaction to dressing
4.3. Need for secondary interventions (incl. need for surgery, admission to hospital, iv antibiotics)
5. Patient-reported outcome measures at week 0, 9 and 18:
5.1. Patient mobility measured using LifeSpace questionnaire
5.2. Wound-related quality of life measured using EQ-5D-5L and Cardiff Wound Impact Questionnaire
5.3. Pain associated with diabetic foot ulcer measured using Visual Analogue Score
6. Patient satisfaction of comfort and impact of dressing, measured using questionnaire at week 18
7. Feasibility of full RCT assessed using:
7.1. Number of eligible patients who consent to participating in the pilot trial
7.2. Recruitment to planned schedule and timelines.
7.3. Withdrawal rates
7.4. Attrition rates

Completion date
31/12/2020

Eligibility

Key inclusion criteria

1. Clinical diagnosis of a Foot Ulcer, present on area that is measurable with a grid sheet (this can include plantar, calcaneus, dorsal, hallux, apex, toe, or ankle-based ulcers). This includes DFU, peripheral arterial disease related wound, or other aetiology. Ulcer should not penetrate the tendon, periosteum or bone
2. Foot ulcer present for at least 6 weeks
3. Adult patients aged >18 years
4. Mental capacity to give consent
5. At least one of the following factors:
5.1. Poorly controlled diabetes (Hba1c > 8% / 64 mmol/mol measured within last 6 months)
5.2. Multiple concurrent foot ulcers
5.3. Recurrence of wounds
5.4. Wound present for more than 18 weeks
5.5. Peripheral arterial disease
5.6. Poor compliance with best practice in foot ulcer management, including non-optimal use of off-loading device

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. Under the age of 18 years
2. Unable to fully understand the consent process and provide informed consent due to either language barriers or mental capacity
3. Limited life expectancy, i.e. undergoing palliative care
4. Active infection in foot ulcer that cannot be managed in podiatry service (ie requires specialist secondary care intervention)
5. Currently receiving antibiotics (topical or systemic), or within one week of receiving antibiotics.
6. Patients who are participating in another research study involving an investigational product that is related to the DFU or a co-morbidity that may influence wound healing (incl diabetes, peripheral arterial disease, immune disorder)
7. The patient has concurrent (medical) conditions that in the opinion of the investigator may compromise patient safety or study objectives, including alcohol or drug dependency.
8. Foot ulcer in area of the foot which would make ulcer size measurement impossible
9. Patient pregnant, actively planning to become pregnant, or lactating
10. Ankle brachial index < 0.6, measured within 3 months of baseline visit (if ABPI cannot be established due to diabetes complications, and podiatrist is confident – on basis of clinical

information - that ABPI is > 0.6 then patient can be enrolled)
11. Any condition that is contraindicated for the use of any of the dressings used in this trial. This includes the earlier mentioned pregnancy, but also severe renal impairment (< 30 ml/min/1.73m2, see https://bnf.nice.org.uk/guidance/prescribing-in-renal-impairment.html), concomitant use of lithium, and thyroid disease (medically diagnosed hypo- or hyperthyroidism, thyroid cancer and/or use of thyroid medication)

Date of first enrolment
28/01/2019

Date of final enrolment
31/07/2020

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Cumbria Partnership NHS Foundation Trust
Carleton Clinic
Carlisle
United Kingdom
CA1 3SX

Sponsor information

Organisation
Cumbria Partnership NHS Foundation Trust

Funder(s)

Funder type
Industry

Funder Name
BSN medical GmbH

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet version v1.1	11/11/2025	11/11/2025	No	Yes
Protocol file		05/11/2018	25/01/2019	No	No