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Evaluation of the WOUNDCHEK point-of-care test for infection in the management of foot and leg ulcers

Submission date
14/07/2023

Recruitment status
No longer recruiting

Registration date
17/07/2023

Overall study status
Completed

Last Edited
25/09/2024

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic ulcer wounds of the legs and feet can be challenging for healthcare staff to manage. Patients often have co-morbidities and there is a considerable likelihood of non-healing and recurrence of ulcers, plus infection can occur. Apart from having a significant negative impact on patients' lives, it is also a huge economic burden to the National Health Service. Clinical opinion – by checking for hallmark signs of infection - is the main way to determine if a wound is infected. Microbiology testing offers information on what type of antibiotic may help to treat the infection. Different companies have developed point-of-care tests that assess something that cannot be readily observed: bacterial protease activity. Its presence may be indicative of infection since bacteria use said protease enzymes to break down protein structures in a wound that are needed for a wound to heal. Due to logistic and cost reasons it would not be practical to apply a protease point-of-care test for all patients' wounds. This study investigates to what degree clinical opinion and results of the WOUNDCHEK Bacterial Status test align, and also what factors and variables may be associated with non-matching results. Furthermore, the degree of influence the WOUNCHEK test result may have on clinical management of chronic lower limb ulcers will be explored.

Who can participate?
Patients aged 18 years or older, with leg and foot ulcers.

What does the study involve?
A total of 258 wounds (minimum of 129 patients) will be assessed at baseline and then six and twelve weeks later.
A WOUNCHEK test is done at week 0 (baseline) and week 6 of the patient's participation in the study when their wound is tended to by their regular clinical staff. This involves a simple swab of the wound, and the swab is then placed on a test strip (similar to a covid19 test). We will evaluate if the clinician's opinion – of whether the wound is infected – matches well with the WOUNDCHEK test result. Apart from the clinical staff being able to change the management of the patient's wound once the test result is known, patient care is not affected. At week 12 a final study visit takes place to see how well the wound is healing.

What are the possible benefits and risks of participating?
The possible benefits for patients is that the WOUNDCHEK test may detect a negative effect of bacteria present in a wound when clinical staff may not see this by visually appraising the wound. This may then mean that the ulcer wound is treated with eg antibacterial dressing instead of normal dressing. There are no anticipated risks associated with the study and the WOUNDCHEK device since testing only involves one additional swab of the wound and no major invasive procedures.

Where is the study run from?
North Cumbria Integrated Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2023 to May 2024

Who is funding the study?
Woundchek Laboratories BV (UK)

Who is the main contact?
Dr Leon Jonker, Leon.jonker@ncic.nhs.uk

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
314595

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55141, IRAS 314595

Study information

Scientific Title
Prospective, single-centre, cohort study assessing the potential application of WOUNDCHEK™ diagnostics for ulcer management

Acronym
BIOME study

Study objectives
Determine what patient and/or wound characteristic(s) are significantly linked to a non-matching result between clinical opinion and WOUNDCHEK™ Bacterial Status (WCBS) result.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/02/2023, North West - Greater Manchester South Research Ethics Committee (3rd Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ, United Kingdom; +44 207 104 8143; gmsouth.rec@hra.nhs.uk), ref: 23/NW/0044

Study design
Interventional non-randomized trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Chronic ulcer wounds of the legs and feet

Interventions
Written informed consent will be taken from the patients. Patients will be in the study for 12 weeks, with outcome measures being taken at week0 week6, and week12. At week0 and week6, their ulcer will be tested for the presence of bacterial infection with the Woundchek Bacterial

Status point-of-care test.
At baseline (week0), 6 weeks and 12 weeks, various validated questionnaires will be completed by the participant (focussing on quality of life and pain) and essential clinical information related to the ulcer (wound healed or not, checking for clinical signs of infection, wound size with PUSH score) will be recorded.
As mentioned, relevant baseline clinical information and any changes in the condition of the leg and patient will be recorded too, including any safety outcomes.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
WOUNDCHEK Bacterial Status test

Primary outcome measure
1. WOUNDCHEK test for presence of wound infection is done at weeks 0 and 6.
2. General quality of life questionnaire (EQ-5D-5L) is done at weeks 0, 6, and 12.
3. Ulcer related pain (visual display scale) is measured at weeks 0, 6, and 12.
4. Ulcer is assessed – as long as its still present – for characteristics like purulence, erythema and odour at weeks 0,6, and 12.
5. Wound size is measured with validated PUSH score at weeks 0, 6 , and 12.
6. Any deviation from original clinical treatment plan (due to WOUNDCHEK result) is recorded at weeks 0 and 6.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/02/2023

Completion date
30/05/2024

Eligibility

Key inclusion criteria
1. Adult patients aged > = 18 years
2. Patients can be newly presenting to or existing users of the specialist service in question (eg podiatry, vascular surgery)
3. Patients with recurrent wounds, including multiple wounds, are eligible; largest ulcer to be index wound
4. If infection occurs and antibiotics applied, whilst in study, then this is not deemed an exclusion criterion.
5. Prophylactic systemic antibiotic use is not an exclusion criterion

6. Chronicity: clinical diagnosis of ulcer with wound duration > 30 days.
7. Wound type:
7.1. Leg ulcer (can be venous, mixed or arterial in nature)
7.2. Foot ulcer (can be diabetic or non-diabetic in nature)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 129; UK Sample Size: 129

Total final enrolment
131

Key exclusion criteria
1. Aged < 18 years
2. Any reasons for the patient being unable to follow the protocol, including lack of mental capacity to consent to taking part in the study.
3. The patient has concurrent (medical) conditions that in the opinion of the investigator may compromise patient safety or study objectives
4. Confirmed and ongoing wound infection at baseline which is already being treated with systemic antibiotics.
5. Previous participation in BIOME study

Date of first enrolment
01/02/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cumberland Infirmary
Newtown Road

Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
North Cumbria Integrated Care NHS Foundation Trust

Sponsor details
Pillars Building
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Sponsor type
Hospital/treatment centre

Website
https://www.ncic.nhs.uk/

ROR
https://ror.org/003hq9m95

Funder(s)

Funder type
Industry

Funder Name
Woundchek Laboratories BV

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date

30/08/2024

Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary

Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	27/01/2023	14/07/2023	No	Yes
Protocol file	version 1	18/11/2022	14/07/2023	No	No
Results article		13/09/2024	25/09/2024	Yes	No