

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

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<b>Registration date</b> 17/07/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/09/2024	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> 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 WOUNDCHEK 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 WOUNDCHEK 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

Dr Leon Jonker

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

314595

### Protocol serial number

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

## Study type(s)

Diagnostic

## 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

## Phase

Not Applicable

**Drug/device/biological/vaccine name(s)**

WOUNDCHEK Bacterial Status test

**Primary outcome(s)**

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.

**Key secondary outcome(s)**

There are no secondary outcome measures

**Completion date**

30/05/2024

## Eligibility

**Key inclusion criteria**

1. Adult patients aged  $\geq 18$  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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

### **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**

United Kingdom

England

### **Study participating centre**

**Cumberland Infirmary**

Newtown Road

Carlisle

United Kingdom

CA2 7HY

## **Sponsor information**

### **Organisation**

North Cumbria Integrated Care NHS Foundation Trust

### **ROR**

<https://ror.org/003hq9m95>

# Funder(s)

## Funder type

Industry

## Funder Name

Woundchek Laboratories BV

# Results and Publications

## 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?
<a href="#">Results article</a>		13/09/2024	25/09/2024	Yes	No
<a href="#">Participant information sheet</a>	version 1.1	27/01/2023	14/07/2023	No	Yes
<a href="#">Protocol file</a>	version 1	18/11/2022	14/07/2023	No	No