

Diabetic foot ulcer infection prevention study

Submission date 29/01/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/02/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/03/2025	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Wound infections are one of the risk factors leading to diabetic foot ulcer deterioration, burdensome follow-up treatments, and toe/foot amputation. Infection prevention and management is therefore a key aspect in treating such wounds. The capability of the study products to prevent infection has been investigated mainly in acute wounds. This study aims to gain more insight into this preventive effect in hard-to-heal wounds, e.g., diabetic foot ulcers.

Who can participate?

Adult patients with diabetes and an ulcer (neuropathic, ischemic, and/or neuroischaemic)

What does the study involve?

Study participation is planned to be 12 weeks. During this time, participants are expected to come to the study site 4 times for examinations and to participate in 9 short study examinations during routinely scheduled dressing changes and/or wound inspections. During each of these study visits, the wound will be examined for various criteria (signs of infection, size of the wound, and wound pain etc.). At the beginning of the study, participants will be randomly allocated into one of the two study groups (arms) (one arm being the control arm which is the common standard of care and the second arm being the test group in which the study products will be used in addition to to the standard-of-care). The study products have been used in wound care for several years. In addition, participants will at the study start and end be asked to complete a quality-of-life questionnaire. Further, they will be asked questions about treatment experiences and satisfaction at the final study visit.

What are the possible benefits and risks of participating?

Possible benefits for you: Both products have been successfully used in wound care for a long time. In both study arms the standard of care will be used to treat the wound. This ensures that in the context of this study, regardless of which group participants are in, they will always receive wound care that meets the common medical standard. During your study participation, data will be collected to help improve the care of this type of wound in the future. They may not necessarily be able to see these benefits for themselves during the study but may help future patients who are being treated for similar wounds.

Potential risks and exposures: The products used in this study have been approved worldwide for a long time, and there already exists a lot of data on safety and tolerability. Experience with

the products in the past does not show an increased incidence of undesirable side effects and the general risk is estimated to be very low. Nevertheless, risks in treatment with wound dressings can never be completely ruled out: allergic reactions may occur, and redness or itching could require additional treatment.

Where is the study run from?

University Hospitals of Derby and Burton NHS Foundation Trust, UK

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

May 2024 to December 2026

Who is funding the study?

BSN medical GmbH

Who is the main contact?

Dr Hardy Schweigel, hardy.schweigel@essity.com

Contact information

Type(s)

Public, Scientific

Contact name

Dr Hardy Schweigel

Contact details

BSN medical GmbH

Schützenstraße 1-3

Hamburg

Germany

22761

+4915227752954

hardy.schweigel@essity.com

Type(s)

Principal Investigator

Contact name

Dr Paul Chadwick

Contact details

3 Blackburn Street

Manchester

United Kingdom

M251FT

+4915227752954

paul.chad@live.co.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

347528

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

C3206, CPMS 60798

Study information

Scientific Title

Prospective, multicenter, parallel, open-label, randomized, controlled trial to investigate the ability of Cutimed® Sorbact® to decrease the risk of infections in subjects with non-infected diabetic foot ulcers compared to standard of care

Study objectives

The primary statistical hypothesis evaluated in this study relates to the primary endpoint. The null and alternative hypothesis are given by:

H0:

Among patients with diabetic foot ulcers (DFUs), the proportion of DFUs that become infected over a 12-week treatment period is equal between those treated with Sorbact® in addition to standard of care (SOC) and those under SOC alone.

H1:

Among patients with DFUs, the proportion of DFUs that become infected over a 12-week treatment period is lower for patients treated with Sorbact® in addition to SOC compared to those under SOC alone.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/01/2025, London - Dulwich Research Ethics Committee (80 London Road, London, SE1 6LH, United Kingdom; +44 (0)207 104 8290; dulwich.rec@hra.nhs.uk), ref: 24/LO/0889

Study design

Postmarket multicenter randomized controlled parallel-arm open-label adaptive study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital, Other therapist office, Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Non-infected superficial diabetes-related foot ulcers

Interventions

The investigation aims to evaluate the preventive effect of Sorbact® gel dressing and Sorbact® swab when used in conjunction with standard of care (SOC) compared with the control arm SOC.

Control: Treatment of diabetic foot ulcer according to SOC as described in NICE guideline NG-19.

Test: Treatment of the ulcer using a monolayer of a dialkylcarbomoyl chloride (DACC)-coated wound dressing (Sorbact Swab or Sorbact Gel) plus the standard-of-care as defined in NICE guideline NG-19. In both arms, treatments will be done whenever medically needed, study documentation is updated weekly. Randomization: The treatments are randomised within blocks with variable sizes. The respective block sizes are themselves randomised to avoid prediction.

Study participation is planned to be 12 weeks. During this time, participants are expected to come to the study site 4 times for examinations and to participate in 9 short study examinations during routinely scheduled dressing changes and/or wound inspections. During each of these study visits, the wound will be examined for various criteria (signs of infection, size of the wound, and wound pain etc.). At the beginning of the study, participants will be randomly allocated into one of the two study groups (arms) (one arm being the control arm which is the common standard of care and the second arm being the test group in which the study products will be used in addition to the standard-of-care). The study products have been used in wound care for several years. In addition, participants will at the study start and end be asked to complete a quality-of-life questionnaire. Further, they will be asked questions about treatment experiences and satisfaction at the final study visit.

Intervention Type

Device

Pharmaceutical study type(s)

Not Applicable

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Cutimed® Sorbact®

Primary outcome measure

Infections in non-infected diabetic foot ulcers (DFUs) measured by a clinician using the International Working Group on the Diabetic Foot (IWGDF) criteria for wound infection at baseline, and weeks 4,8 and 12

Secondary outcome measures

1. Infection signs and description, as defined by the IWGDF guideline 2023, measured by a clinician weekly and an assessment of general wound pain measured using a visual analogue scale (VAS) at baseline, and weeks 4, 8 and 12
2. Changes to the wound including the appearance of the wound and peri-wound skin as well as the wound size measured by a clinician with a wound ruler at baseline, and weeks 4, 8 and 12
3. Sorbact® device use in the test arm measured by self-reporting of the dressing used and dressing change frequency at baseline, and weeks 4, 8 and 12
4. Health-related quality of life measured using the EQ-5D-5L questionnaire at baseline and week 12, with satisfaction measured at the final visit only
5. Healthcare provider's (HCPs) assessment of treatment success and HCPs satisfaction measured using self-reporting at week 12
6. Sorbact® device safety measured by self-reporting device deficiencies at every study visit

Overall study start date

01/05/2024

Completion date

21/12/2026

Eligibility

Key inclusion criteria

General criteria:

1. At least 18 years old
2. The subject understands and is willing to participate in the clinical study (written informed consent) and can comply with required visits
3. The subject has diabetes and an ulcer (neuropathic, ischemic, and/or neuroischaemic)
4. Diagnosis of either type I or type II diabetes with glycosylated haemoglobin HbA1c ≤ 108 (12%)
5. The target ulcer will be the largest ulcer if two or more eligible DFUs are present and will be the only one evaluated in the study
6. The target ulcer is planned to undergo standard wound care (SWC) therapy

Ulcer criteria:

1. Non-infected according to IWGDF 2023
2. WIFI (Wound 1, Ischemia 0,1,2 and Infection 0)
3. Wound area $> 1 \text{ cm}^2$
4. Ulcer not older than 12 weeks
5. Superficial ulcer not involving tendon, capsule or bone
6. Systemic and/or topical antibiotic treatment wash out of at least 48 hours)
7. Treatment with any antimicrobial dressing wash out of at least 7 days

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

550 enrolled

Key exclusion criteria

1. Target ulcer is deemed by the investigator to be caused by a medical condition other than diabetes.
2. Target ulcer, in the opinion of the investigator, is suspicious for cancer and should undergo an ulcer biopsy to rule out a carcinoma of the ulcer.
3. Eligible DFU has associated untreated acute or chronic osteomyelitis or abscess.
4. Clinically infected ulcer (IWGDF 2023: ≥ 2 signs of infection)
5. Subjects with a history of more than two weeks treatment with immunosuppressants (including systemic corticosteroids $>10\text{mg}$ daily dose), cytotoxic chemotherapy.
6. Pregnant or breast-feeding patients
7. Subject not deemed suitable by the principle investigator for another reason.
8. Sensitivity or allergy to any product component.
9. Participation in another pharmaceutical or medical device study within the last 30 days.
10. Employee (staff or student) of the hospital site (institute) or the sponsor or is in a dependent relationship with a member of site or sponsor staff, e.g. child, spouse etc.

Date of first enrolment

01/04/2025

Date of final enrolment

01/10/2026

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospitals of Derby and Burton NHS Foundation Trust

Royal Derby Hospital

Uttoxeter Road

Derby

United Kingdom

DE22 3NE

Sponsor information

Organisation

BSN medical GmbH

Sponsor details

Schützenstraße 1-3

Hamburg

Germany

22761

+46761077156

markus.wittebo@essity.com

Sponsor type

Industry

Website

<https://www.essity.com/>

Funder(s)**Funder type**

Industry

Funder Name

BSN medical GmbH

Results and Publications**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

Intention to publish date

21/12/2026

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository (<https://www.castoredc.com/>)

IPD sharing plan summary

Stored in non-publicly available repository