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Diabetic foot ulcer infection prevention study

Submission date
29/01/2025

Recruitment status
Recruiting

Registration date
03/02/2025

Overall study status
Ongoing

Last Edited
07/10/2026

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 March 2028

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, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
347528

Central Portfolio Management System (CPMS)
60798

Protocol serial number
C3206

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

Primary study design
Interventional

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

Study type(s)
Prevention

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 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

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cutimed® Sorbact®

Primary outcome(s)
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

Key secondary outcome(s)
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

Completion date
31/03/2028

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 cm2
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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
150 Years

Sex
All

Total final enrolment
0

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 >10mg 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
31/12/2027

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road
Derby
England
DE22 3NE

Sponsor information

Organisation
BSN medical GmbH

Funder(s)

Funder type
Industry

Funder Name
BSN medical GmbH

Results and Publications

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