

Laboratory observational Ex-Vivo study to investigate the sensitivity and specificity of a smart dressing to detect clinically relevant wound infection

Submission date 24/10/2016	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 09/12/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 17/08/2021	Condition category Skin and Connective Tissue Diseases	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Burn wound infections are difficult to diagnose, but may become serious if they are not treated quickly. To diagnose an infection, dressings need to be removed from the wound, which may slow the healing process. A new dressing Smartwound™ may help to diagnose wound infection without needing to remove the dressing. The Smartwound™ dressing changes colour in the presence of the infection-causing bacteria. Laboratory studies show that the dressing does change colour in the presence of bacteria, but before it can be used in patients, it needs to be tested with the bacteria found in human wounds. The new Smartwound™ dressing will not be tested on patients in this study. Samples of burn wound fluid, called exudate, which can be taken from wound swabs and used wound dressings when the patients have their dressings removed will be used. Exudate will be gathered from patients with and without wound infection to see whether the dressing changes colour in the presence of the bacteria that cause a wound infection. Dressing changes and swabs are part of the normal care routine for patients with burns. This study aims to test whether the Smartwound™ technology developed to detect infection in a dressing for burn wounds is effective in identifying infection.

Who can participate?

Patients with burn wounds who either have a suspected infection requiring a dressing change and patients with a burn injury with no signs of an infected wound.

What does the study involve?

Old standard dressings are collected from patients along with some samples of the burn wound exudate/biofilm (burn wound fluid) using gauze and two cotton swabs. The samples of exudate are taken from the patients during routine treatment. This may be when they are in theatre or in the treatment area, when the wound is being cleaned. The new Smartwound™ dressing is not being tested on patients. The exudate samples are used to test the Smartwound™ dressing in the laboratory. Some medical information relating to the burn wound is collected. Patients are followed up at 14- 21 days to gain information about antibiotic treatment, dressings, additional

medical help and the healing of the burn wound. This is done either at scheduled clinic appointments as part of normal care, or by telephone.

What are the possible benefits and risks of participating?

There are no direct benefits or risks involved to those participating.

Where is the study run from?

1. Bristol Royal Hospital for Children (UK)
2. Southmead Hospital (UK)
3. Queen Victoria Hospital in East Grinstead (UK)
4. Chelsea and Westminster Hospital (UK)

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

June 2015 to April 2018

Who is funding the study?

Medical Research Council (UK)

Who is the main contact?

Dr Natasha Iles

BSCTUEvident@bsms.ac.uk

Contact information

Type(s)

Public

Contact name

Dr Natasha Iles

Contact details

Brighton and Sussex Clinical Trials Unit

Room 204 Bevendean House

University of Brighton

Brighton

United Kingdom

BN1 9PH

Additional identifiers

Protocol serial number

CH/2016/6025

Study information

Scientific Title

Laboratory observational Ex-Vivo study to investigate the sensitivity and specificity of a smart dressing to detect clinically relevant wound infection

Acronym

EVIDEnT: Ex Vivo Infection DETection

Study objectives

The aim of this diagnostic accuracy study is to estimate the sensitivity, specificity, for the infection detection 'smart' technology.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South West - Cornwall & Plymouth Research Ethics Committee, 02/09/2016, ref: 16/SW/0238

Primary study design

Observational

Study design

Multi-centre prospective ex-vivo diagnostic technology development study

Study type(s)

Other

Health condition(s) or problem(s) studied

Burn wound infection

Interventions

The old dressing and exudate soaked gauze will be sent to the laboratory at University of Bath to assess the smart wound technology 'switch-on' i.e. colour change. A standard swab will be sent for routine hospital microbiology analysis (MC+S) and a clinical assessment of wound infection by observation will be performed. A swab will also be sent to the laboratory at University of Brighton for qPCR testing to determine the levels of bacterial toxins present to validate the technology responsiveness and the clinical definition of wound infection. The patient will be followed up by means of a telephone call or face-to-face if they have a routine visit scheduled at 14-21 days for a retrospective confirmation of whether the wound was infected or not.

Intervention Type

Biological/Vaccine

Primary outcome(s)

1. Technology switched on or remained off is measured by observing colour change in the laboratory at baseline
2. Clinically relevant wound infection or no infection is assessed using clinical decisions, taking into account observation of wound, laboratory markers of inflammation and infection, wound and blood microscopy and culture and response to antibiotics at baseline. A follow-up review at 14-21 days will be carried out to confirm retrospectively the wound infection assessment at baseline.

Key secondary outcome(s)

Levels of bacterial toxins to validate both clinical definition of wound infection and technology switch-on is measured using qPCR at baseline.

Completion date

24/04/2018

Eligibility

Key inclusion criteria**Control group**

1. Patients with burns of all types and sizes
2. Any child from 4 weeks up to the age of 16 years/adults up to 100 years
3. >48 hrs after injury but before healing complete
4. Wound dressings intact
5. No signs of wound infection
6. Not currently using antibiotics
7. Consent gained for study

Suspected infection group

1. Patients who present with a suspected burn wound infection as determined by the reference standard.
2. A child/adult with burns
3. Any child from 4 weeks up to the age of 16 years/adults up to 100 years
4. Wound dressings intact
5. Not on antibiotics for longer than 24 hours
6. Consent gained for study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

Total final enrolment

344

Key exclusion criteria**All participants:**

1. Child < four weeks of age/adults above 100 years
2. Consent not gained for study
3. Adult without mental capacity to consent
4. A child/adult who is on antibiotics for longer than 24 hours
5. No wound dressings

Date of first enrolment

13/01/2017

Date of final enrolment

26/04/2018

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Bristol Royal Hospital for Children**

Paul O'Gorman Building

Upper Maudlin Street

Bristol

United Kingdom

BS2 8BJ

Study participating centre**Southmead Hospital**

Dorian Way

Westbury-on-Trym

Bristol

United Kingdom

BS10 5NB

Study participating centre**Queen Victoria Hospital**

Holtye Road

East Grinstead

United Kingdom

RH19 3DZ

Study participating centre**Chelsea and Westminster Hospital**

369 Fulham Road

London

United Kingdom

SW10 9NH

Sponsor information

Organisation

University Hospitals Bristol NHS Foundation Trust

ROR

<https://ror.org/04nm1cv11>

Funder(s)

Funder type

Research council

Funder Name

Medical Research Council

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	version V2.2	30/09/2016	09/12/2016	No	Yes
Participant information sheet	version V2.2	30/09/2016	09/12/2016	No	Yes

Participant information sheet	version V2.2	30/09/2016	09/12/2016	No	Yes
Participant information sheet	version V2.2	30/09/2016	09/12/2016	No	Yes
Preprint results	preprint results	23/07/2021	17/08/2021	No	No