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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

Registration date
09/12/2016

Overall study status
Completed

Last Edited
17/08/2021

Condition category
Skin and Connective Tissue Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Contact information

Type(s)
Public

Contact name
Dr Natasha Iles

Contact details
Brighton and Sussex Clinical Trials Unit
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Multi-centre prospective ex-vivo diagnostic technology development study

Primary study design
Observational

Secondary study design
Laboratory study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

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 would 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 measure
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.

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

Overall study start date
01/06/2015

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

Age group
Mixed

Sex
Both

Target number of participants
322 with suspected infection, and 100 controls (plus 20 with suspected infection, 10 controls for the pilot phase)

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
England

United Kingdom

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

Sponsor details
Research & Innovation
Education & Research Centre
Level 3
Upper Maudlin Street
Bristol
England
United Kingdom
BS2 8AE

Sponsor type
Hospital/treatment centre

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, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

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

Intention to publish date
26/04/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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
HRA research summary			28/06/2023	No	No