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A clinical trial looking at the efficacy and optimal dose of acetic acid in burn wound infections

Submission date
18/12/2017

Recruitment status
No longer recruiting

Registration date
29/01/2018

Overall study status
Completed

Last Edited
09/01/2025

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
Burn wound infections (BWI) can cause delayed healing of burns, poor scarring and infection leading to sepsis. Acetic acid is more commonly known as vinegar and has been used as an antibacterial agent for thousands of years. More recently it has been a widely used antiseptic agent for use on skin for the treatment of burns wounds and has been shown to have activity against certain bacterial infections within the wounds. During the treatment of these wounds, it is important to maintain a balance between effective removal of bacteria and how well patients tolerate the acetic acid. It is documented that many patients complain of stinging and pain on application of acetic acid to wounds, in particular if a strength of 5% concentration is used. The study will assess how two different strengths of acetic acid (0.5 and 2% concentrations) are tolerated by patients who have been admitted to hospital with burn wound infections. The study aims to establish the optimal dose of acetic acid for treating colonised burns wounds. The burns wounds will require to be colonised with a specifically identifiable bacteria and bacteria load will be studied by the microbiology department. Wound exudate extracted for burns dressing will be examined alongside routine burns swabs to extract detailed data of bacterial load and acetic acid presence.

Who can participate?
People aged 16 years and older who have a burn injury.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group have their burns treated with dressings soaked in 0.5% acetic acid solution. Those in the second group have their burns treated with dressings soaked in 2% acetic acid solution. Participants undergo twice daily dressing changes for a period of 3 days (except on day 3 when only one dressing change will take place). There is a total of five dressing changes throughout the study period, which are equivalent to usual treatment for these patients. The duration of the study also falls under usual treatment. At each dressing change patients are asked to record their pain experience before pain relief, after burn wound cleaning and before treatment, immediately after treatment and 30 minutes after treatment. The dressings removed from patients containing wound fluid are

then sent to the microbiology laboratory for further testing and examination. The burn wound surface pH (which shows how acidic the wound is) is also measured during each dressing change as this there is evidence to suggest that wound surface pH relates to the healing time. Once daily (during the morning dressing change) participants also have a microbiology wound swab taken from their burn wounds to investigate the levels and types of bacteria in their wound. The date that the wound is 95% healed will be recorded in the Prescribing Information and Communication System (PICS).

What are the possible benefits and risks of participating?
There are no known additional benefits for being a participant in the study, but by testing out these lower concentrations of acetic acid in treating burns wounds this may lead to patients experiencing less pain and stinging if these concentrations are found to be as effective (as higher concentrations currently used) and are used as standard treatment in the future.

Where is the study run from?
Queen Elizabeth Hospital Birmingham (UK)

When is the study starting and how long is it expected to run for?
February 2017 to January 2022

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Miss Gurneet Sur, g.sur@bham.ac.uk

Contact information

Type(s)
Scientific

Contact name
Miss Gurneet Sur

Contact details
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Additional identifiers

Clinical Trials Information System (CTIS)

2017-003481-28

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 36451

Study information

Scientific Title
A pilot randomised controlled trial to examine the efficacy and optimal dose of acetic acid to treat colonised burns wounds

Acronym
AceticA

Study objectives
The study aims to establish the optimal dose of acetic acid for treating colonised burns wounds. The burns wounds will require to be colonised with a specifically identifiable bacteria and bacteria load will be studied by the microbiology department. Wound exudate extracted for burns dressing will be examined alongside routine burns swabs to extract detailed data of bacterial load and acetic acid presence.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands – Edgbaston REC Committee, 21/12/2017, ref: 17/WM/0407

Study design
Randomized; Interventional; Design type: Treatment, Other

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Burn wound infections

Interventions
Current intervention as of 27/11/2020:
Patients are admitted to QEHB following a burn injury, those with a burn ≥1% TBSA (Total Body Surface Area) that is colonised with bacteria and who meet the eligibility criteria are provided with details of the study along with a Patient Information Sheet. If they provide fully informed written consent they are then enrolled onto the study and randomised to receive treatment of

the burn wounds via dressings soaked in either 0.5% of 2% acetic acid solution. The trial is double-blinded hence neither the treating clinical team or the participants know which concentration of acetic acid they have been randomised to.

Once on the trial the participants undergo twice daily dressing changes for a period of 3 days (except on day 3 when only one dressing change will take place). There is a total of five dressing changes throughout the study period, which is equivalent to standard-of-care for these patients. The duration of the study also fall under the patient's standard-of-care. At each dressing change patients are asked to complete a Visual Analogue Scale (VAS) at four time-points to record their pain experience prior to analgesia, post burn wound cleaning and prior to treatment, immediately post treatment and 30 minutes post treatment. The dressings removed from patients containing wound exudate are then sent to the microbiology laboratory for further testing and examination. The burn wound surface pH are also measured during each dressing change as this there is evidence to suggest that wound surface pH correlates to the time of healing. Once daily (during the morning dressing change) participants also have a microbiology wound swab taken from their burn wounds. The date that the treated area has reached 95% healing will be collected as part of the trial data; this data can be retrospectively obtained from the Prescribing Information and Communication System (PICS) at the end of the trial.

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Previous intervention:
Patients are admitted to QEHB following a burn injury, those with a burn ≥1% TBSA (Total Body Surface Area) that is colonised with a bacteria and who meet the eligibility criteria are provided with details of the study along with a Patient Information Sheet. If they provide fully informed written consent they are then enrolled onto the study and randomised to receive treatment of the burn wounds via dressings soaked in either 0.5% of 2% acetic acid solution. The trial is double-blinded hence neither the treating clinical team or the participants know which concentration of acetic acid they have been randomised to.

Once on the trial the participants undergo twice daily dressing changes for a period of five days (except on day three when only one dressing change will take place). There is a total of nine dressing changes throughout the study period, which are equivalent to standard-of-care for these patients. The duration of the study also fall under the patient's standard-of-care. At each dressing change patients are asked to complete a Visual Analogue Scale (VAS) at four time-points to record their pain experience prior to analgesia, post burn wound cleaning and prior to treatment, immediately post treatment and 30 minutes post treatment. The dressings removed from patients containing wound exudate are then sent to the microbiology laboratory for further testing and examination. The burn wound surface pH are also measured during each dressing change as this there is evidence to suggest that wound surface pH correlates to the time of healing. Once daily (during the morning dressing change) participants also have a microbiology wound swab taken from their burn wounds. Participants are followed up at day 21 post burn injury, which fall in line with their standard of care hence participants have not have to attend this solely for trial-specific purposes.

Intervention Type
Other

Phase
Phase II

Primary outcome(s)

Current primary outcome measure as of 27/11/2020:
Efficacy will be assessed by measuring the bacterial load from microbiology burn wound swabs taken daily from the beginning of treatment for 3 days

Previous primary outcome measures:
1. Tolerability of acetic acid are assessed by measuring patients' pain scores with a Visual Analogue Scale (VAS) over the 5 day treatment period
2. Efficacy of acetic acid are assessed by measuring the bacterial load from microbiology wound swabs, these will be taken daily from recruitment for 5 consecutive days

Key secondary outcome(s))
Current secondary outcome measures as of 27/11/2020:
1. Tolerability will be assessed by measuring a patient's pain scores with a Visual Analogue Scale (VAS) on patients who have capacity to complete scores at each dressing change
2. The antimicrobial activity of acetic acid will be measured by extracting fluid from removed burns dressings at each dressing change and assessing the minimum inhibitory concentrations (MIC) to establish if active acetic acid is still present
3. Time to 95% healing of treated area
4. Perceived treatment allocation, assessed by asking patients after treatment completion which treatment they believed they received

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Previous secondary outcome measures:
1. The antimicrobial activity of acetic acid are measured by extracting fluid from removed burns dressings and assessing the minimum inhibitory concentrations (MIC) to establish if active acetic acid is still present
2. Percentage of burn wound healed at 21 days (+/- 3 days) post burn injury
3. Perceived treatment allocation is assessed by asking patients after treatment completion (after the last dressing change on day 5) which treatment they believed they received

Completion date
04/01/2022

Eligibility

Key inclusion criteria
Current inclusion criteria as of 27/11/2020:
1. At least one ≥1% TBSA burn injury prior to enrolment
2. Burn wound colonised with a specifically identifiable bacterium
3. Aged ≥16 years old
4. Anticipated to remain as inpatient for the study duration i.e. 3 days

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Previous inclusion criteria as of 03/08/2018:
1. Patient to have a ≥1% TBSA burn injury/ies prior to enrolment
2. Burn wound colonised with a specifically identifiable bacteria
3. Patients aged ≥18 years old
4. Patients who are anticipated to remain as inpatients for the study duration i.e. 5 days

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Previous inclusion criteria:
1. Patient to have a 1 - <10 % TBSA burn injury prior to enrolment
2. Burn wound colonised with a specifically identifiable bacteria
3. Patients aged ≥18 years old
4. Patients who are anticipated to remain as inpatients for the study duration i.e. 5 day

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
16 years

Sex
All

Total final enrolment
22

Key exclusion criteria
Current inclusion criteria as of 27/11/2020:
1. Burns solely to the face and/or genital area
2. Patients who have received acetic acid as part of standard therapy upon admission to inpatients for this burn injury
3. Patients deemed unsuitable to enter trial in the opinion of the investigator

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Previous exclusion criteria as of 03/08/2018:
1. Patients who lack capacity to give informed consent (NB: translation services will be available for non-English speaking patients)
2. Patients who are on antibiotics for cellulitis
3. Patients with burns solely to the face and/or genital area
4. Patients who have received acetic acid as part of standard therapy upon admission to inpatients for this burn injury
5. Patients deemed unsuitable to enter trial in the opinion of the investigator

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Previous exclusion criteria:
1. Patients who lack capacity to give informed consent (NB: translation services will be available for non-English speaking patients)
2. Patients who are receiving systemic antibiotics
3. Patients with burns solely to the face and/or genital area

4. Patients who have received acetic acid as part of standard therapy upon admission to inpatients for this burn injury
5. Patients deemed unsuitable to enter trial in the opinion of the investigator

Date of first enrolment
01/02/2018

Date of final enrolment
22/11/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Queen Elizabeth Hospital Birmingham
University Hospitals Birmingham NHS Foundation Trust
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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 and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	version 1.0	25/09/2023	26/09/2023	Yes	No
Basic results		29/01/2024	09/01/2025	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes