

# Trial of MRSA decolonisation treatment in adult hospital in-patients

<b>Submission date</b> 12/04/2022	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/06/2022	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 20/10/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Bacteria such as *Staphylococcus aureus* (*S. aureus*) live on and around us without causing harm. Patients coming into hospital who carry *S. aureus* in the nose and skin are at increased risk of developing infections if the bacteria access areas such as the site of surgery or a drip to give fluid or drugs. These infections are difficult to treat when a resistance to penicillin has built up, known as methicillin-resistant *S. aureus* (MRSA). To reduce the risk of getting an infection while in hospital, many patients are routinely “decolonised” of the *S. aureus* bacteria. This usually involves the patient applying a nasal ointment, mupirocin (a type of antibiotic), three times daily for 5 days and using a body wash. Some *S. aureus* is resistant to mupirocin so it is not good to rely on a single treatment. This study will look at two alternatives to find out if they are as effective as mupirocin. The different treatments are already used in the NHS.

### Who can participate?

In-patients aged 16 years or over who are found to carry MRSA after a routine screening swab on admission

### What does the study involve?

Participants will be put in one of three groups at random. One group will be given the usual treatment of nasal mupirocin, the second will use an antiseptic and the third group an antibiotic. This is a randomised study and neither the patient nor the clinician will choose the group. All three groups will use body wash for 5 days. Nasal swabs will be taken 48 hours and 4 weeks after finishing treatment and the number of successful nasal decolonisations will be compared.

### What are the possible benefits and risks of participating?

The researchers plan to include participants who are unable to give consent for themselves, such as people with dementia. This is a vulnerable group, but it is important to ensure they are included as they make up a large proportion of those at risk.

The results will be shared throughout the NHS, charities and those who write guidelines for doctors. The researchers will write a summary of the results for patients, families, carers and all those who help deliver the trial in NHS hospital.

In the context of a lack of robust evidence to determine the best intervention for patients with MRSA colonisation, the risks are not increased through trial participation. However, there are

risks associated with this study, which are associated with all study treatments. Patients will be screened for MRSA upon admission, in line with routine hospital policy. There will be no additional baseline swab, however, patients will be required to have two additional follow up nasal swabs for the study. The participant information sheets (PISs) will be developed with the involvement of our Patient Advisory Group (PAG) and will give a balanced account of the possible benefits and known risks of the interventions. It will state explicitly that quality of care will not be compromised if the individual decides not to enter the trial or to withdraw their consent. The researchers will make it clear that there is no obligation to participate.

Where is the study run from?

South Tees Hospitals NHS Foundation Trust (UK)

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

April 2022 to October 2024

Who is funding the study?

NIHR Health Technology Assessment Programme (UK)

Who is the main contact?

1. Liz Cook, [liz.cook@york.ac.uk](mailto:liz.cook@york.ac.uk)

2. Prof. Mike Reed, [mike.reed@nhs.net](mailto:mike.reed@nhs.net)

### **Study website**

<https://www.york.ac.uk/healthsciences/research/trials/ytutrialsandstudies/trials/tide/>

## **Contact information**

### **Type(s)**

Public

### **Contact name**

Mrs Liz Cook

### **ORCID ID**

<http://orcid.org/0000-0001-6902-0235>

### **Contact details**

University of York

Heslington

York

United Kingdom

YO19 6TA

+44 (0)1904 321522

[liz.cook@york.ac.uk](mailto:liz.cook@york.ac.uk)

### **Type(s)**

Scientific

### **Contact name**

Prof Mike Reed

**Contact details**

Wansbeck District General Hospital  
Ashington  
United Kingdom  
NE63 9JJ  
+44 (0)7834 665847  
mike.reed@nhs.net

**Type(s)**

Principal Investigator

**Contact name**

Prof Mike Reed

**Contact details**

Wansbeck District General Hospital  
Woodhorn Lane  
Ashington  
United Kingdom  
NE63 9JJ  
+44 (0)7834 665847  
mike.reed@nhs.net

**Additional identifiers****EudraCT/CTIS number**

2021-006732-96

**IRAS number**

1004425

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

IRAS 1004425, CPMS 51774

**Study information****Scientific Title**

A multi-centre, randomised controlled, non-inferiority and cost-effectiveness trial comparing polyhexanide and chlorhexidine with neomycin to mupirocin for nasal methicillin-resistant *Staphylococcus aureus* (MRSA) decolonisation amongst adult hospital in-patients

**Acronym**

TIDE

**Study objectives**

**Primary Objective:**

To undertake a multi-centre, three-arm parallel-group, non-inferiority randomised controlled trial (RCT) to determine whether nasal polyhexanide gel or nasal chlorhexidine with neomycin cream is not inferior to nasal mupirocin ointment when each is accompanied with chlorhexidine body wash or wipes, for early nasal decolonisation of methicillin-resistant *Staphylococcus aureus* (MRSA) amongst adult hospital in-patients

1. Undertake a 9-month internal pilot to confirm the feasibility of the study, in particular recruitment rate and completeness of follow-up.
2. Undertake an embedded qualitative study during the internal pilot study to optimise recruitment and consent processes with a particular focus on underserved and vulnerable populations.
3. Undertake a cost-effectiveness analysis of the three interventions from the NHS perspective to identify the most efficient provision of future NHS care.
4. Undertake an analysis of secondary outcomes.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 01/06/2022, East Midlands - Derby Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; Tel: not available; derby.rec@hra.nhs.uk), ref: 22/EM/0096

**Study design**

Randomized controlled open parallel-group trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

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

**Health condition(s) or problem(s) studied**

Methicillin-resistant *Staphylococcus aureus* (MRSA) positive colonisation

**Interventions**

This is a multi-centre, pragmatic, randomised controlled non-inferiority trial, with an internal pilot phase to check the assumptions about recruitment and provide guidance on optimising the trial processes. This study will be carried out in up to 25 NHS hospitals within the UK with

facilities to support research activity. A total of 3000 (1000 in each of three arms) male and female patients will be recruited for the study. Prior to study involvement, patients will be given a participant information sheet to read and be given sufficient time to consider this information.

Eligible and consenting patients will be randomly allocated to one of three treatments:

1. Mupirocin (2%) nasal ointment (3 g): applied to the inner surface of each nostril three times a day for 5 days.
2. Polyhexanide (0.1%) nasal gel (30 ml): applied to the inner surface of each nostril three times a day for 5 days.
3. Chlorhexidine (0.1%) with neomycin (0.5%) nasal cream (15g): applied to the inner surface of each nostril four times a day for 10 days.

All the nasal products will be provided in conjunction with chlorhexidine (4% body wash or 2% skin wipes dependent on existing recruiting Trust practices) for bathing/ showering/ washing for five days. Participants will be informed of their treatment allocation. Participants will receive all other medical care as per standard of care. The researchers will assess outcomes at the start of the study, then at 48 hours and 4 weeks after treatment has been completed. The associated costs of the three treatments to the NHS will also be evaluated.

### **Intervention Type**

Mixed

### **Primary outcome measure**

Successful early nasal decolonisation, defined as a negative trial-specific nasal MRSA swab taken 48 hours following treatment completion

### **Secondary outcome measures**

1. Successful early nasal decolonisation of MRSA not fully susceptible to mupirocin; sensitivities will be determined from a routine swab taken at baseline
2. Successful early nasal decolonisation of MRSA not fully susceptible to gentamicin (used as a marker of neomycin); sensitivities will be determined from a routine swab taken at baseline
3. Successful late nasal decolonisation, defined as a negative trial-specific nasal MRSA swab taken 4 weeks following treatment completion
4. Acceptability of treatment to patients measured using a Likert scale at 48 hours following the completion of treatment
5. MRSA infections: any confirmed MRSA infections (e.g., skin and wound infections, joint infections, endocarditis, pneumonia and bacteraemia), obtained from patient medical records or patient self-report up to 4 weeks following completion of treatment
6. Total length of hospital in-patient stays, obtained from patient medical records, up to 4 weeks following completion of treatment
7. Total length of hospital in-patient stays for patients diagnosed with an MRSA infection, obtained from patients' medical records, up to 4 weeks following completion of treatment
8. Hospital readmissions, obtained from patients' medical records, up to 4 weeks following completion of treatment
9. Adverse events obtained from patients' medical records or patient self-report up to 4 weeks following completion of treatment
10. Mortality obtained from patients' medical records up to 4 weeks following completion of treatment

### **Overall study start date**

08/04/2022

**Completion date**

31/10/2024

**Reason abandoned (if study stopped)**

Objectives no longer viable

## Eligibility

**Key inclusion criteria**

1. Adult in-patient (aged 16 years old or over)
2. Eligible for MRSA screening on admission, based on the local hospital infection control policy, who are found to be colonised with MRSA

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

16 Years

**Sex**

Both

**Target number of participants**

3000

**Total final enrolment**

32

**Key exclusion criteria**

1. Known hypersensitivity to study treatment(s) or excipients
2. Allergy to peanut and/or soya
3. Day-case admissions
4. Patients identified to be colonised with MRSA in the outpatient setting
5. Previous participation in the TIDE trial or current participation in another trial of a medicinal product that does not allow co-enrolment
6. Patients actively undergoing another decolonisation treatment at the time of recruitment
7. Medical history that might, in the opinion of the attending clinician, put the patient at significant risk if they were to participate in the trial

**Date of first enrolment**

31/10/2022

**Date of final enrolment**

31/07/2023

## Locations

**Countries of recruitment**

England

Scotland

United Kingdom

**Study participating centre****James Cook University Hospital**

Marton Road

Middlesbrough

United Kingdom

TS4 3BW

**Study participating centre****North Tyneside General Hospital**

Rake Lane

North Shields

United Kingdom

NE29 8NH

**Study participating centre****Kings Mill Hospital**

Mansfield Road

Sutton-in-ashfield

United Kingdom

NG17 4JL

**Study participating centre****Pinderfields Hospital**

Aberford Road

Wakefield

United Kingdom

WF1 4DG

**Study participating centre****Western General Hospital**

Crewe Road South

Edinburgh

Lothian  
United Kingdom  
EH4 2XU

**Study participating centre**

**Musgrove Park Hospital**

Taunton  
United Kingdom  
TA1 5DA

**Study participating centre**

**Milton Keynes University Hospital NHS Foundation Trust**

Standing Way  
Eaglestone  
Milton Keynes  
United Kingdom  
MK6 5LD

**Study participating centre**

**York and Scarborough Teaching Hospitals NHS Foundation Trust**

York Hospital  
Wigginton Road  
York  
United Kingdom  
YO31 8HE

**Study participating centre**

**Mid and South Essex NHS Foundation Trust**

Prittlewell Chase  
Westcliff-on-sea  
United Kingdom  
SS0 0RY

## **Sponsor information**

**Organisation**

South Tees Hospitals NHS Foundation Trust

**Sponsor details**



Durham Tees Valley Research Alliance (DTVRA)  
The James Cook University Hospital  
Marton Road  
Middlesbrough  
England  
United Kingdom  
TS4 3BW  
+44 (0)1642 854089  
dtvra.projects@nhs.net

**Sponsor type**

University/education

**Website**

<http://southtees.nhs.uk/>

**ROR**

<https://ror.org/02js17r36>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## **Results and Publications**

**Publication and dissemination plan**

1. Peer-reviewed scientific journals
2. Internal report
3. Conference presentation

- 4. Publication on website
- 5. Other publication
- 6. Other

### Intention to publish date

31/10/2025

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study (fully anonymised) will be available upon request after the publication of the study results from Prof. Catherine Hewitt (catherine.hewitt@york.ac.uk). Participants will be informed that information collected about them may be shared anonymously with other researchers and will be asked to consent to this.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No