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A feasibility study to assess the acceptability of Staphylococcus aureus decolonisation to prevent skin and soft tissue infections

Submission date
23/04/2024

Recruitment status
Recruiting

Registration date
31/01/2025

Overall study status
Ongoing

Last Edited
01/07/2025

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
Skin and soft tissue infections (SSTIs), particularly those associated with the bacteria Staphylococcus aureus (S.aureus), are common in certain UK populations such as military, prison personnel, returning travellers, children and sport teams. Of concern is the ability of certain strains like Panton-Valentine Leukocidin S.aureus (PVL-SA) and methicillin-resistant S.aureus (MRSA) to cause outbreaks of boils and abscesses, impacting on the health of the individual and their household. Furthermore, SSTIs lead to hospital admissions and recurrent antibiotic use. Nasal carriage of S.aureus can increase a risk of infections following certain procedures: dialysis, cardiothoracic and orthopaedic surgery and so now it is routine to decolonise these patients using a body treatment (nasal ointment and skin wash). This feasibility study will assess the acceptability of routine decolonisation on S. aureus carriage and SSTIs using a high-risk military population at the Infantry Training Centre (ITC), Catterick.

Who can participate?
Military recruits aged 16 - 35.5 years

What does the study involve?
Military recruits at ITC will be consented and then randomised to receive weekly decolonization therapy (mupirocin nasal ointment and Hibiscrub body wash/shampoo) or mupirocin and octenisan with 25 consented participants in each group. The feasibility study will assess the acceptability of decolonisation to the study participant and healthcare worker involved using an electronic database called OpenClinica. The study will assess the ability to collect study outcomes (SSTI rates, antimicrobial resistance of colonising bacteria, referral to secondary care, serious adverse events and use of point of care testing). The study will last for 12 weeks.

What are the possible benefits and risks of participating?
The participation of individuals will support the refinement of military clinical guidance and provide information for future research. There are potential minor adverse effects associated with certain elements of the study, such as discomfort from having a swab and this will be minimise by training and involving the participant in the sampling. There is the possibility of

intolerance or reactions to the decolonisation regimens and anyone with a known reaction will be excluded.

Where is the study run from?
Infantry Training Centre, Catterick (UK)
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
April 2024 to June 2026

Who is funding the study?
Defence Medical Services Research Strategy Group (UK)

Who is the main contact?
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Contact information

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Scientific, Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
24IC8767

Study information

Scientific Title
A feasibility study to assess the acceptability of Staphylococcus aureus decolonisation to prevent skin and soft tissue infections

Study objectives
The main aim of the feasibility project will be to assess the acceptability of weekly Staphylococcus aureus decolonisation using hIbiscrub and bactroban or octenisan and bactroban to prevent against skin and soft tissue infections. The data from the feasibility study will inform future research and current guidance.

In order to meet the main aim the feasibility study will assess:
- the acceptability of decolonisation to the consented participant
- the willingness of individuals to adhere to the decolonisation and collection of samples
- the willingness of study participants and clinical teams to be involved
- the assessment of processes including monitoring of any serious adverse events, hospital admission rates and change in antimicrobial resistance rates of S.aureus carriage rates.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 25/07/2024, Ministry of Defence Research Ethics Committee (DSTL Portondown West, Fareham, PO17 6AD, United Kingdom; +44 (0)300 153 5372; DST-MODRECTeam@mod.gov.uk), ref: 2297/MOD/24

Study design
Interventional randomized controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised feasibility trial

Study setting(s)
Other

Study type(s)
Safety

Participant information sheet

Health condition(s) or problem(s) studied
Acceptability of S.aureus decolonisation to prevent against skin and soft tissue infections in military recruits

Interventions
The feasibility study will assess the acceptability of S.aureus decolonisation to prevent skin and soft tissue infections. Prior to decolonisation individuals will be screen for S.aureus at 4 body sites. Individuals will be randomised to receive decolonisation therapy weekly either: chlorhexidine 4% body wash and shampoo with mupirocin 2% nasal ointment or octenisan body wash and shampoo with mupirocin 2% nasal ointment.

Intervention Type
Drug

Pharmaceutical study type(s)
Prophylaxis, Therapy, Others (This is a feasibility study to assess the acceptability of decolonisation to prevent against skin and soft tissue infection to allow the refinement of a future study.)

Phase
Phase I

Drug/device/biological/vaccine name(s)
Bactroban 2% ointment (2% w/w mupirocin free acid) [Mupirocin 2%], Chlorhexidine 4% (Hibiscrub) [Chlorhexidine Gluconate 40 mg/ml (4.0% w/v).]

Primary outcome measure
Incidence of skin and soft tissue infection at time frame 12 weeks recorded in each individual participants Defence Medical Information Capability programme (DMICP).

Secondary outcome measures
1. Admission to Primary care facility or secondary care recorded in each individual participants DMICP record. Time frame 12 weeks.
2. Serious adverse events measured using questionnaires at 1, 4 and 12 weeks.

3. Antimicrobial resistance rates of Staphylococcus aureus acquired from 4 body sites (nose, throat, axilla and groin) using bacterial swabs at 3 time points 1, 4 and 12 weeks.

Overall study start date
19/04/2024

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Over the age of 16 years and below 35 years and 6 months
2. Military and deemed fit to attend phase 1 training

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
16 Years

Upper age limit
35.5 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
A participant will be excluded from the study if deemed inappropriate by the IMO or ITC Medical Staff

Date of first enrolment
25/02/2025

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Infantry Training Centre (ITC)
Catterick
United Kingdom
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Sponsor information

Organisation
Imperial College London

Sponsor details
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Sponsor type
University/education

Website
http://www.imperial.ac.uk/

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Government

Funder Name
Defence Medical Services Research Clinical Innovation

Results and Publications

Publication and dissemination plan

Peer reviewed scientific journals
Internal report
Conference presentation
Publication on website
Other publication
Submission to regulatory authorities
The feasibility study will be registered with ClinicalTrials.gov. The results will be shared with the Academic Department of Military medicine and collaborators with the study (UK HSA, Staphylococcal reference laboratory). All data will be anonymous.

Intention to publish date
01/10/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to confidentiality.

IPD sharing plan summary
Not expected to be made available