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A randomised controlled trial of tea tree oil (5%) body wash versus standard body wash to prevent colonisation with methicillin-resistant Staphylococcus aureus in critically ill adults

Submission date
18/05/2007

Recruitment status
No longer recruiting

Registration date
16/08/2007

Overall study status
Completed

Last Edited
16/06/2014

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
EAT/3460/06

Study information

Scientific Title

Study objectives
Methicillin-Resistant Staphylococcus Aureus (MRSA) colonisation among critically ill patients is reduced by daily washing with 5% Tea Tree Oil (TTO) body wash in comparison with standard body wash (Johnson's pH 5.5).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. School of Nursing and Midwifery Research Ethics Committee at Queen's University Belfast, 16 /04/2007, ref: 03 2007
2. Office for Research Ethics Committees Northern Ireland, 03/09/2007, ref: 07/NIR03/71

Study design
Single-centre phase II/III prospective open-label randomised controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Critical illness; Methicillin-Resistant Staphylococcus Aureus (MRSA)

Interventions
A proprietary 5% tea tree oil-enriched body wash preparation versus standard body wash (Johnson's pH 5.5). The duration of treatment is for the length of the patient's ICU stay. Follow up will be until hospital discharge.

Intervention Type

Drug

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
5% Tea Tree Oil

Primary outcome measure
New MRSA colonisation during the inpatient episode in RICU, as defined by detection of MRSA by conventional culture methods in screening swabs of nose and groin, or in clinical specimens processed by the laboratory in the course of normal clinical care. This will be measured on discharge from the ICU.

Secondary outcome measures
All measured on discharge from the ICU:
1. Cost-effectiveness of regular use of 5% TTO body wash in this context
2. MRSA bacteraemia rates
3. Consumption of antibiotics used for the treatment of MRSA infection
4. Changes in the Sequential Organ Failure Assessment (SOFA) score during ICU stay

Overall study start date
30/07/2007

Completion date
30/07/2010

Eligibility

Key inclusion criteria
Patients admitted to the Intensive Care Unit (ICU) during the study period will be eligible for inclusion in the study.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
1080

Key exclusion criteria
1. Aged less than 16 years
2. Those patients who are known to be colonised at the time of admission
3. Patients who on admission are unlikely to remain in the Respiratory Intensive Care Unit (RICU) for at least 48 hours

4. Patients who are recruited, whose pre-intervention MRSA screening tests are subsequently found to be positive, will be withdrawn from the study
5. Consent declined
6. Known sensitivity to TTO

Date of first enrolment
30/07/2007

Date of final enrolment
30/07/2010

Locations

Countries of recruitment
Northern Ireland

United Kingdom

Study participating centre
Nursing and Midwifery Research Unit
Belfast
United Kingdom
BT9 5AF

Sponsor information

Organisation
Belfast Health and Social Care Trust (UK)

Sponsor details
Royal Victoria Hospital
Grosvenor Road
Belfast
Northern Ireland
United Kingdom
BT12 6BA
+44 (0)28 9024 0503
i.young@qub.ac.uk

Sponsor type
Hospital/treatment centre

Website
http://www.belfasttrust.hscni.net/

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
The Research and Development Office, Northern Ireland (UK) (ref: EAT/3460/06)

Funder Name
REVIVE - Charity for the Regional Intensive Care Unit, Royal Victoria Hospital (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	28/11/2008		Yes	No
Results article	results	01/05/2013		Yes	No