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	Recruitment status No longer recruiting	Prospectively registered		
18/05/2007		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/08/2007	Completed	[X] Results		
Last Edited 16/06/2014	Condition category Infections and Infestations	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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Contact details

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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