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Whole body washing to reduce skin-surface bacteria: pilot study in healthy volunteers

Submission date	Recruitment status	[_] Prospectively registered
31/03/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2019	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of three body washing products to reduce bacterial colony forming units on skin: a pilot study in healthy volunteers

Study objectives
What is the difference in the reduction of colony forming units on skin between three body washing products, using pre-intervention and three post intervention time points?

This is a pilot study to investigate which product is most effective at reducing bacteria on skin. Skin bacteria can cause surgical site infections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Faculty of Health and Life Sciences Research Ethics Committee, De Montfort University, 04/02/2010, ref: 584

Study design
Pilot randomised active controlled parallel-group trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Surgical site infections

Interventions
Participants randomised to 1 of 3 groups using random number tables and sequentially numbered sealed envelopes
1. Group 1 Control: Plain soap and plain shampoo
Participants shower daily for two days using the following instructions -
Enter shower, ensure body and hair are wet. Apply 25mls soap to body, rinse and repeat using another 25mls. Wash hair. Rinse thoroughly. Dry with a clean towel.

2. Group 2 Intervention: Hibiscrub® Plus
Participants shower daily for two days following manufacturers instructions -
Enter shower, ensure body and hair are wet. Apply 25mls Hibiscrub® Plus to body, rinse and repeat using another 25mls. Wash hair. Rinse thoroughly. Dry with a clean towel.

3. Group 3 Intervention: Octenisan®
Participants shower daily for five days following manufacturers instructions -
Enter shower, ensure body and hair are wet. Apply Octenisan® to a damp cloth and apply to body. Leave for 3 minutes before rinsing thoroughly. Wash hair with Octenisan® on day 2 and day 4. Dry with a clean towel.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Colony forming units from swabs taken from nose, armpit and groin pre-intervention and post intervention at 0 hours, 4 hours and 6 hours.

Secondary outcome measures
None

Overall study start date
01/03/2010

Completion date
21/05/2010

Eligibility

Key inclusion criteria
1. Healthy volunteers from De Montfort University - staff or students
2. Any age and either sex

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
60 participants spread across 3 groups. 20 participants in each group (pilot study)

Total final enrolment
60

Key exclusion criteria
1. Allergic to soaps, Hibiscrub® Plus or Octenisan®
2. Has an open wound
3. Currently taking antibiotics or has taken antibiotics in the previous week
4. Has a respiratory infection
5. Has a skin infection
6. Wears jewellery in nose
7. Wears moisturiser, body lotion or any other antiseptic skin product

Date of first enrolment
01/03/2010

Date of final enrolment
21/05/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
De Montfort University
Leicester
United Kingdom
LE2 1RQ

Sponsor information

Organisation
De Montfort University (UK)

Sponsor details
The Gateway
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Sponsor type
University/education

ROR
https://ror.org/0312pnr83

Funder(s)

Funder type
Industry

Funder Name
Molnlycke Health Care (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?
Results article	results	01/01/2012	31/10/2019	Yes	No