

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

Submission date
31/03/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
07/04/2010

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
31/10/2019

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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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

Leicester

England

United Kingdom

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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