

# 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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### Contact details

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## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Prevention

## **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(s)**

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

**Key secondary outcome(s)**

None

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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**

United Kingdom

England

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

## Sponsor information

**Organisation**  
De Montfort University (UK)

**ROR**  
<https://ror.org/0312pnr83>

## Funder(s)

**Funder type**  
Industry

**Funder Name**  
Molnlycke Health Care (UK)

## Results and Publications

**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?
<a href="#">Results article</a>	results	01/01/2012	31/10/2019	Yes	No