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

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

#### Contact name

Prof Judith Tanner

### 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

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?
Results article	results	01/01/2012 31/10/2019 Yes	No

Participant information sheet 11/11/2025 No Yes