# Suppression of surgeons skin flora during surgical procedures using a new antimicrobial surgical glove

Submission date	Recruitment status	Prospectively registered
22/04/2012	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
08/05/2012	Completed	[X] Results
Last Edited	Condition category	Individual participant data
21/01/2019	Infections and Infestations	

# Plain English summary of protocol

Background and study aims

A surgical site is the incision or cut in the skin made by a surgeon to carry out a surgical procedure, and the tissue handled or manipulated during the procedure. If holes develop in the surgeon's gloves, this can lead to skin micro-organisms contaminating the surgical site. This can lead to a surgical site infection. Sterile surgical gloves have been developed that are coated inside with the antibacterial chlorhexidine to protect healthcare workers from infection in case of glove puncture. The aim of this study is to find out whether antimicrobial gloves might reduce the risk of contamination of the surgical site in the event of a glove puncture.

Who can participate?

Surgeons and patients undergoing heart surgery

What does the study involve?

Patients are operated on following the same standard for all patients cared for at the Wilhelminen Hospital Vienna. The only difference is that surgical staff members wear one antimicrobial glove and one

standard glove on either hand. At the end of the study, the number of bacteria found on the gloves and the hands of the surgeons are compared.

What are the possible benefits and risks of participating?

There are no benefits to those taking part, but there should be benefits to future surgical patients if there are fewer bacteria on the hands wearing antimicrobial gloves, as this could help lower the number of infections after surgical procedures. The only possible risk for participants would be an allergic reaction to chlorhexidine, which would not be fatal and is extremely unlikely as the amount of chlorhexidine on the gloves is small.

Where is the study run from? Wilhelminen Hospital Vienna (Austria)

When is the study starting and how long is it expected to run for? November 2011 to February 2012

Who is funding the study?

- 1. Medical University of Vienna (Austria)
- 2. Ansell Ltd (Australia)

Who is the main contact?
Prof. Ojan Assadian
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# Contact information

# Type(s)

Scientific

#### Contact name

Prof Ojan Assadian

#### Contact details

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# Additional identifiers

Protocol serial number AMT-HAND 01/11

# Study information

#### Scientific Title

Prospective, double-blind, randomized controlled single-centre trial: suppression of surgeons skin flora during surgical procedures using a new antimicrobial surgical glove

# Study objectives

A novel sterile antimicrobial surgical glove, featuring a proprietary complex coating with 14 ingredients and chlorhexidine as active ingredient on its inner surface has been developed. It was hypothesised that this antimicrobial glove might reduce the risk of contamination of the surgical site in the event of an intraoperative breach of the integrity of the glove by suppression of re-growth of skin flora during the course of a surgical procedure.

# Ethics approval required

Old ethics approval format

## Ethics approval(s)

City of Vienna Ethics Committee, 10/02/2012, ref: EK 11-201-1111

# Study design

Phase III randomized controlled double-blind single-centre trial

## Primary study design

Interventional

## Study type(s)

Prevention

# Health condition(s) or problem(s) studied

Prevention of surgical site infection

#### **Interventions**

The main target size is the number of glove pairs, and not the number of patients. Patients will be operated on following the same standard for all patients cared for at the Department for Vascular and Endovascular Surgery of the Wilhelminen Hospital Vienna. The only difference is that 1 up to 3 surgical staff member will wear one antimicrobial and one standard non-antimicrobial sterile surgical glove on either hand. The allocation of gloves per surgeon will be randomized.

#### Intervention Type

Other

#### Phase

Phase III

# Primary outcome(s)

The number of colony forming units per mL (cfu/mL) in glove juice collected in real-time conditions after surgical procedures in the operating theatre (OT)

# Key secondary outcome(s))

The differences in the bacterial skin population of surgeons hands during surgical procedures under antimicrobial or non-antimicrobial surgical gloves

# Completion date

03/02/2012

# Eligibility

# Key inclusion criteria

Surgeons:

- 1. All surgeons agreeing to participate after appropriate orientation and instruction
- 2. Surgeons with visibly healthy skin, without cuts or abrasions, and individuals who had not used medicated soap or medicated hand creams one week prior to the test run

#### Patients:

- 1. All patients undergoing carotid endarterectomy, aortic reconstruction for aneurysms or occlusive disease, or open surgical bypass for peripheral arterial occlusive disease, are eligible to be included into the study if no existing infection at any site is present.
- 2. Patients must not have a re-operation during the subsequent 30 days before the study

## Participant type(s)

Mixed

# Healthy volunteers allowed

No

## Age group

Adult

#### Sex

Αll

#### Key exclusion criteria

#### Surgeons:

- 1. Individuals without visibly healthy skin, with cuts or abrasions, and individuals who had used medicated soap or medicated hand creams one week prior to the test run
- 2. The use of alcohol-based hand rubs containing no additional compounds with a sustained antimicrobial efficacy 24 hours before testing

#### Patients:

- 1. All patients for which all other procedures are performed than carotid endarterectomy, aortic reconstruction for aneurysms or occlusive disease, or open surgical bypass for peripheral arterial occlusive disease
- 2. All patients with an existing infection at any site and patients having a re-operation during the subsequent 30 days

#### Date of first enrolment

17/11/2011

#### Date of final enrolment

03/02/2012

# Locations

#### Countries of recruitment

Austria

# Study participating centre Medical University of Vienna

Vienna Austria 1090

# Sponsor information

#### Organisation

Ansell Healthcare (Belgium)

# Funder(s)

## Funder type

University/education

#### Funder Name

Medizinische Universität Wien

## Alternative Name(s)

Medical University of Vienna, MediUni Wien

#### **Funding Body Type**

Government organisation

# Funding Body Subtype

Local government

#### Location

Austria

#### **Funder Name**

Ansell Ltd, Richmond (Australia)

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type Details
Results article results