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

Submission date
22/04/2012

Recruitment status
No longer recruiting

Registration date
08/05/2012

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

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 measure
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)

Secondary outcome measures

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

Overall study start date
17/11/2011

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

Age group
Adult

Sex
Both

Target number of participants
26 surgeons and a maximum of 26 patients

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)

Sponsor details
EMEA Headquarters
Riverside Business Park
Block J
Boulevard International 55
Brussels
Belgium
B-1070

Sponsor type
Industry

Website
http://www.eu-ansell.com

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

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	01/02/2014	21/01/2019	Yes	No