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The efficacy of Prontoderm® for topical decolonisation of methicillin-resistant Staphylococcus aureus (MRSA) carriers

Submission date	Recruitment status	[_] Prospectively registered
23/12/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/03/2011	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/10/2015	Infections and Infestations	

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

10-085

Study information

Scientific Title
A double-blind, randomised, single centre study to evaluate the efficacy of polyhexanide (Prontoderm®) versus placebo for topical decolonisation of methicillin-resistant Staphylococcus aureus (MRSA) carriers

Study objectives
There is no difference with regard to suppressing or eliminating methicillin-resistant Staphylococcus aureus (MRSA) carriage in patients treated at the Geneva University Hospitals between topical administration of Prontoderm® (containing polyhexanide) and placebo (identical with the marketed product, except for the absence of polyhexanide) for 10 days.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee (Comité départemental d'éthique de médecine interne et médecine communautaire, Hôpitaux Universitaires de Genève), 25/08/2010, ref: 10-085

Study design
Double-blind randomised placebo-controlled single centre interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
MRSA asymptomatic colonisation

Interventions
Patients who consent to take part in the trial will be randomised to topical treatment with either Prontoderm® or placebo for 10 days. Two preparations of the investigational products will be used, a solution and a gel. The solution should be applied once a day to the hair and scalp using 3 - 5 single-use wash cloths. A sufficient amount of gel (ca. 0.5 - 1 mL) should be applied to the anterior nares in a circular motion three times a day using cotton swabs. A sufficient amount of

gel (ca. 0.5 - 1 mL) should also be applied once a day to the entry site of catheters, if present, using a fresh sterile cotton swab for each site (working outwards).

Total duration of treatment = 10 days
Total duration of follow-up = 28 days from the end of treatment

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Prontoderm®

Primary outcome measure
Decolonisation of MRSA carriage, expressed as the proportion of participants with a complete set of microbiologically negative swabs (nose and groin/perineum) at day 28 after the end of treatment

Secondary outcome measures
1. Suppression of MRSA colonisation, expressed as the proportion of participants with a complete set of microbiologically negative swabs at day 2 after the end of treatment, irrespective of any subsequent culture results
2. Development of resistance to polyhexanide during the study defined as a statistically significant increase in the minimum inhibitory concentration in MRSA isolated at any time after the end of treatment
3. Adverse effects reported by patients (Irritation of the skin (redness, dryness, itch) or the anterior nares (dryness, itch) indicated on a scale from 0 - 5 (0 = none, 1 = trace, 2 = mild, 3 = moderate, 4 = severe and 5 = very severe)

Overall study start date
05/01/2011

Completion date
30/09/2012

Eligibility

Key inclusion criteria
1. Aged greater than or equal to 18 years, either sex
2. Microbiologically documented MRSA carriage at any site, without any signs and symptoms of active MRSA infection
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Active MRSA infection
2. Chronic ulcers and deep-seated wounds colonized by MRSA
3. Presence of tracheostomy
4. Presence of external fixator colonised with MRSA
5. Unavailability of adequate help if subject is unable to self-administer the investigational product
6. Concurrent treatment with antimicrobial agents with anti-MRSA activity at the time of enrollment
7. Participation in another prospective clinical trial
8. Previous enrollment in the proposed study
9. Inability to understand or to follow the study protocol
10. Planned cardiac or orthopaedic implant surgery
11. Known or suspected hypersensitivity or allergy to any of the study drugs
12. Known hypersensitivity to chlorhexidine
13. Pregnancy or breastfeeding
14. Current or planned treatment with other agents that are topically applied to the skin or the nares
15. Critically ill patients hospitalised in the intensive care unit

Date of first enrolment
05/01/2011

Date of final enrolment
30/09/2012

Locations

Countries of recruitment
Switzerland

Study participating centre
Hôpitaux Universitaires de Genève
Genève 14
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Sponsor information

Organisation
Geneva University Hospitals (Hôpitaux Universitaires de Genève) (Switzerland)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.hug-ge.ch/

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Industry

Funder Name
B. Braun Medical AG (Switzerland)

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	01/02/2016		Yes	No