ISRCTN02288276 https://doi.org/10.1186/ISRCTN02288276

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

Submission date
23/12/2010

Recruitment status
No longer recruiting

Registration date
04/03/2011

Overall study status
Completed

Last Edited
29/10/2015

Condition category
Infections and Infestations

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Stephan Harbarth

Contact details
Service prévention et contrôle de l'infection
Hôpitaux Universitaires de Genève
Rue Gabrielle-Perret-Gentil 4
Genève 14
Switzerland
1211
-
stephan.harbarth@hcuge.ch

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s)
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
Switzerland
1211

Sponsor information

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

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Industry

Funder Name

B. Braun Medical AG (Switzerland)

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	01/02/2016		Yes	No