ISRCTN56186788 https://doi.org/10.1186/ISRCTN56186788

Prevention of nosocomial Staphylococcus aureus infections after rapid detection and eradication of S. aureus carriage in patients at risk: a randomised placebo controlled multi-center trial

Submission date
20/12/2005

Recruitment status
No longer recruiting

Registration date
20/12/2005

Overall study status
Completed

Last Edited
08/01/2010

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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR348

Study information

Scientific Title

Acronym
STEP study

Study objectives
Nosocomial Staphylococcus aureus infections in S. aureus nasal carriers can be reduced by 50%, by application of mupirocin nasal ointment in combination with washing with chlorhexidine containing soap within 24 hours after admission.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Randomised double blind placebo controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Nosocomial Staphylococcus aureus infection

Interventions
The comparison intervention consists of mupirocin 2% nasal ointment and chlorhexidindigluconate 4% body soap. The control intervention consists of placebo nasal ointment and placebo body soap.

Patients are treated for 5 days: twice daily application of nasal ointment (with the size of a match's head) in both nostrils and once daily washing of the entire body with soap. Patients who are still admitted at 3 weeks and 6 weeks after admission will receive the same study medication again.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Mupirocin, chlorhexidindigluconate

Primary outcome measure
Nosocomial S. aureus infection until 6 weeks after discharge according to Centers for Disease Control and prevention (CDC)-criteria.

Secondary outcome measures
1. Duration of hospital stay
2. In-hospital mortality
3. Time to nosocomial S. aureus infection

Overall study start date
01/10/2005

Completion date
01/04/2007

Eligibility

Key inclusion criteria
1. Adult patients (greater than or equal to 18 years)
2. Rapid detection positive for S. aureus nasal carriage
3. Expected admission of greater than or equal to 4 days
4. Treatment can be started less than or equal to 24 hours after admission
5. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1800

Key exclusion criteria
1. S. aureus infection at enrolment
2. Allergy to mupirocin
3. Allergy to chlorhexidin
4. Pregnancy or lactation
5. Recent (less than 4 weeks) mupirocin use
6. Nasal corpus alienum

Date of first enrolment
01/10/2005

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus Medical Center
Rotterdam
Netherlands
3015 GD

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
Dr Molewaterplein 40/50
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Sponsor type
University/education

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Organization for Health Research and Development (ZonMw) (Netherlands)

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	07/01/2010		Yes	No