

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

☐ Prospectively registered

☐ Protocol

Registration date

20/12/2005

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

08/01/2010

Condition category

Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised double blind placebo controlled parallel group trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

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