STEP study.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28142

Source
NTR

Brief title
STEP study

Health condition

Nosocomial Staphylococcus aureus infection.

Sponsors and support

Primary sponsor: Primary sponsor:
Department of Medical Microbiology and Infectious Disease at Erasmus MC, University Medical Center, Rotterdam, the Netherlands.
Secondary sponsors:
Canisius Wilhelmina hospital, Nijmegen, the Netherlands
Amphia hospital, Breda, the Netherlands
University Medical Center Utrecht, Utrecht, the Netherlands
VU Medical Center, Amsterdam, the Netherlands
Source(s) of monetary or material Support: The Netherlands Organisation for Health Research and Development (ZonMw)

Intervention

Outcome measures

Primary outcome

Nosocomial S. aureus infection until 6 weeks after discharge according to CDC-criteria.

Secondary outcome

1. Duration of hospital stay;

2. In-hospital mortality;

3. Time to nosocomial S. aureus infection.

Study description

Background summary

To assess whether the treatment of S. aureus carriage with mupirocin nasal ointment in combination with skin disinfection (chlorhexidin) significantly reduces nosocomial S. aureus infections in S. aureus carriers, we will conduct a double-blinded placebo controlled multi-center trial. For 18 months patients will be screened for S. aureus nasal carriage at admission through nasal swabs by a rapid molecular technique. Carriers are randomly assigned to receive either mupirocin nasal ointment in combination with disinfecting soap (chlorhexidin) or placebo ointment in combination with placebo disinfecting soap for five consecutive days, starting within 24 hours after admission to the hospital.

Study objective

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 chloorhexidin containing soap within 24 hours after admission.

Study design

N/A

Intervention

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 nares 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.

Contacts

Public
Erasmus Medical Center, Department of Medical Microbiology and Infectious Diseases,
Dr. Molewaterplein 40
Lonneke Bode
Dr. Molewaterplein 40
Rotterdam 3015 GD
The Netherlands
+31 (0)10 4633510 / +31 (0)10 4633511
Scientific
Erasmus Medical Center, Department of Medical Microbiology and Infectious Diseases,
Dr. Molewaterplein 40
Lonneke Bode
Dr. Molewaterplein 40
Rotterdam 3015 GD
The Netherlands
+31 (0)10 4633510 / +31 (0)10 4633511

Eligibility criteria

Inclusion criteria

1. Adult patients (>= 18 years);

2. Rapid detection positive for S. aureus nasal carriage;

3. Expected admission of >= 4 days;

4. Treatment can be started <= 24 hours after admission;

5. Informed consent.

Exclusion criteria

1. S. aureus infection at enrollment;

2. Allergy to mupirocin;

3. Allergy to chlorhexidin;

4. Pregnancy or lactation;

5. Recent (< 4 weeks) mupirocin use;

6. Nasal corpus alienum.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2005
Enrollment:	1800
Type:	Actual

Ethics review

Positive opinion

Date:	21-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL310
NTR-old	NTR348
Other	: N/A
ISRCTN	ISRCTN56186788

Study results

Summary results

CDC definitions for nosocomial infections. J.S. Garner et al. In: Olmsted RN, ed.: APIC Infection control and applied epidemiology: Principles and practice. St. Louis: Mosby; 1996:pp A-1--A-20.
Mupirocin prophylaxis against nosocomial Staphylococcus aureus infections in nonsurgical patients. A randomized study.
H.F.L. Wertheim et al. Ann Intern Med 2004;140:419-25.