

STEP study.

Gepubliceerd: 21-09-2005 Laatste bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28142

Bron

NTR

Verkorte titel

STEP study

Aandoening

Nosocomial Staphylococcus aureus infection.

Ondersteuning

Primaire 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

Overige ondersteuning: The Netherlands Organisation for Health Research and Development (ZonMw)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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 chlorhexidin containing soap within 24 hours after admission.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind
Controle:	Placebo

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2005
Aantal proefpersonen:	1800
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies	
Datum:	21-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

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.