

Wisselwerking tussen S. aureus en andere bacteriën in de neus

Gepubliceerd: 07-09-2018 Laatste bijgewerkt: 15-05-2024

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26095

Bron

Nationaal Trial Register

Verkorte titel

MACOTRA

Aandoening

S. aureus, staphylococcus aureus

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Rotterdam

Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Microbiome composition of the nose

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: This study will investigate the interaction between host nasal microbiome and *Staphylococcus aureus* to elicit the influence of host factors on success of dominant MRSA clones.

Objective: To identify nasal microbial communities associated with *Staphylococcus aureus* carriage and study the influence over time of *S. aureus*-targeted decolonization treatment on these microbial communities.

Study design: Prospective interventional cohort study with 2 groups.

Study population: A total of 70 healthy Dutch volunteers will be recruited to participate in the study. These volunteers will be grouped based on their *S. aureus* carrier status, either as carriers or noncarriers.

Intervention: After inclusion and determination of carrier status, all volunteers will be treated with Mupirocin (Bactroban) 2% nasal ointment and Chlorhexidine gluconate (Hibiscrub®) 4% cutaneous body wash solution within the product indication and in accordance with local clinical practice.

Main study parameters/endpoints: Microbiome composition of the nose, to be analysed in relation to *S. aureus* carrier status and decolonization.

Onderzoeksopzet

After a two-week screening period for *S. aureus* nasal carriage, eligible volunteers are included and followed for 6 months.

Onderzoeksproduct en/of interventie

5 day treatment with Bactroban 2% nasal ointment (mupirocin) and Hibiscrub 4% cutaneous solution (chlorhexidine gluconate) at the start of the study

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Volunteers must be over 18 years old

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Employee of the Erasmus MC
- Intermittent carrier of *Staphylococcus aureus*
- Use of drugs influencing microbiome in 3 months prior to the study period i.e. antibiotics, antiparasitics or antifungals
- Regular use of commercial probiotics in 3 months prior to the study period
- Known allergy to components of the intervention treatment, consisting of mupirocin nasal ointment and chlorhexidine wash
- Pregnant and breastfeeding women, due to limited scientific evidence on adverse effects of

mupirocin treatment during pregnancy and breastfeeding.

- Known chronic diseases affecting the immune system (such as diabetes mellitus, renal insufficiency, COPD, heart diseases, immunocompromised status (HIV, AIDS), skin diseases such as severe eczema or use of immunosuppressant drugs

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	07-09-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48845

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7254
NTR-old	NTR7461
CCMO	NL65791.078.18
OMON	NL-OMON48845

Resultaten

Samenvatting resultaten

Not applicable