The effects of SDD and SOD on antibiotic resistance in the ICU.

Gepubliceerd: 28-04-2009 Laatst bijgewerkt: 18-08-2022

The difference between both interventions is the absence of intestinal decontamination during SOD and the standard use of cephalosporins for all patients during SDD. It has been hypothesized that eradication of the intestinal Gram negative bacterial...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28926

Bron
NTR

Verkorte titel
N/A

Aandoening

SDD, SOD, ICU, antibiotic resistance, selective decontamination

Ondersteuning

Primaire sponsor: University Medical Center Utrecht,
Heidelberglaan 100, 3584 CX, Utrecht
phone +31 (0)887555555
Overige ondersteuning: University Medical Center Utrecht,
Heidelberglaan 100, 3584 CX, Utrecht
phone +31 (0)887555555

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Point prevalence of rectal and respiratory colonization with specificantly defined resistant bacteria (both Gram positive and Gram negative) according to the WIP-guidelines.

Toelichting onderzoek

Achtergrond van het onderzoek

Multicenter, cross-over comparison study of SDD and SOD in ICU settings using either SDD or SOD for standard care. Results from routinely performed clinical and surveillance cultures will be used to assess development of antibiotic resistance in different ‘marker’ pathogens.

Doel van het onderzoek

The difference between both interventions is the absence of intestinal decontamination during SOD and the standard use of cephalosporins for all patients during SDD. It has been hypothesized that eradication of the intestinal Gram negative bacterial flora reduces the likelihood of resistance development in Gram negative bacteria.

Onderzoeksopzet

Each ICU will be randomized into one of two study arms, starting either with SDD or SOD for twelve months, with cross-over to the other intervention. Before starting the first study period and after the
first period, a wash-out wash-in period (1 month) will be carried out, during which the new treatment (either SDD or SOD) will be implemented, but patient data will not be used for analysis.

Onderzoeksproduct en/of interventie

SDD consists of an oropharyngeal application (every 6 h) of a paste containing colistine, tobramycin and amphotericin B each in a 2% concentration, and administration (every 6 h) of a 10 ml suspension containing colistine, tobramycin and amphotericin B via the nasogastric tube. Topical antibiotics will be applied until ICU-discharge. In addition, cefotaxime (1000 mg, every 6 h) will be administered intravenously during the first four days of study.
SOD consists of oropharyngeal application of the same paste as used for SDD.

Contactpersonen

Publiek

University Medical Center Utrecht,
Department of Medical Microbiology,
Postal address G.04.5.17
E. Oostdijk
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands
+31 (0)88 7555006

Wetenschappelijk

University Medical Center Utrecht,
Department of Medical Microbiology,
Postal address G.04.5.17
E. Oostdijk
Heidelberglaan 100
Utrecht 3584 CX
The Netherlands
+31 (0)88 7555006

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients admitted to ICU with an expected length of ICU stay of 48 hours.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients younger than 18 years.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2009
Aantal proefpersonen:	6000
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL1679
NTR-old	NTR1780

Register	ID
Ander register	MEC UMC : 08/097
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A