Tobramycine absorptie bij SDD

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24557

Source
NTR

Health condition

Selective Decontamination of the Digestive tract (SDD), Intensive Care Unit (ICU)

Sponsors and support

Primary sponsor: Martini Ziekenhuis, Groningen
Source(s) of monetary or material Support: Martini Ziekenhuis, Groningen

Intervention

Outcome measures

Primary outcome

Achieving high (> 1,0 mg/L) tobramycin serum concentrations during the use of SDD.

Secondary outcome

Identification of risk factors that contribute to high systemic serum tobramycin concentrations. To this end, we extract data from the patient record in Chipsoft.

Study description

Background summary

SDD is used to prevent infections in ICU patients. It is applied in the mouth and directly in the stomach. There should be no absorption of the SDD components (tobramycin, colistin and amphotericin B), so no serum concentrations are to be expected. However patients with detectable tobramycin serum concentrations have been reported.
This study is an observational cohort study. By taking blood from all patients in the ICU who receive SDD treatment, we want to gain insight into what extent clinically significant systemic absorption of tobramycin occurs and to identify possible risk factors that may contribute to an increased risk of absorption of tobramycin.

Study objective

The purpose of this study is to provide insight into what extent clinically significant systemic absorption of tobramycin occurs (resulting in a serum tobramycin concentration >1,0 mg/L) in ICU and Medium Care ICU patients who are being treated with SDD. In addition, the goal of this research is to gain insight into risk factors that may contribute to an increased risk of absorption of tobramycin in the use of SDD.

Study design

Blood will be taken from the patient on days 3, 7, 10 and 14 after the start of SDD

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

- Signed Informed Consent

- Patient has to lie on the ICU or Medium Care ICU

- Patient has to use SDD

Exclusion criteria

- Patients that are admitted to the burns ICU

- Patients concurrently or within 72 hours prior to SDD treatment receiving tobramycin administered parenterally or pulmonary

- Patients who aren't treated with the regular schedule

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-02-2016
Enrollment:	200
Type:	Actual

Ethics review

Positive opinion
Date: 28-01-2016
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43386
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5541
NTR-old	NTR5661
CCMO	NL55838.099.15
OMON	NL-OMON43386

Study results