

# Absorption of tobramycin from the gut in critically ill patients treated with selective decontamination of the digestive tract (SDD)

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To determine whether tobramycin, administered in the gut, permeates from the gut into the blood and is subsequently excreted into the urine.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Ancillary infectious topics
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON30143

### Source

ToetsingOnline

### Brief title

Absorption of tobramycin during SDD

### Condition

- Ancillary infectious topics

### Synonym

antibiotics, permeability

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Onze Lieve Vrouwe Gasthuis

**Source(s) of monetary or material Support:** eventuele kosten worden betaald door de

vakgroep intensive care

## Intervention

**Keyword:** permeability, selective decontamination of the digestive tract, tobramycin

## Outcome measures

### Primary outcome

concentrations of tobramycin in blood

excretion of tobramycin in urine

### Secondary outcome

renal function

SOFA score

APACHE score

## Study description

### Background summary

For the prevention of pathological colonisation of the digestive tract and subsequent infections critically, ill patients are treated with antibiotics in the gastrointestinal tract. Normally, these antibiotics remain in the gut. During critical illness, gut permeability may be increased. As a result, the enterally administered antibiotics might permeate from the gut to the blood.

### Study objective

To determine whether tobramycin, administered in the gut, permeates from the gut into the blood and is subsequently excreted into the urine.

### Study design

observational cohort pilot study

### Study burden and risks

no burden or risks

## Contacts

### Public

Onze Lieve Vrouwe Gasthuis

Oosterpark 9  
1090 HM Amsterdam  
Nederland

### Scientific

Onze Lieve Vrouwe Gasthuis

Oosterpark 9  
1090 HM Amsterdam  
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Critically ill patients acutely admitted to the intensive care patients, treated with selective decontamination of the digestive tract for at least 24 hours.

### Exclusion criteria

Intravenous use of tobramycin or gentamycin

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-10-2006

Enrollment: 20

Type: Anticipated

## Ethics review

Approved WMO

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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

CCMO

### ID

NL13783.067.06