

# Does continuous cefotaxime administration improve time to attainment and maintenance of target drug levels in intensive care patients?

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Bacterial infectious disorders
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON41771

### Source

ToetsingOnline

### Brief title

Cefotaxime target attainment

### Condition

- Bacterial infectious disorders

### Synonym

bacterial pneumonia, selective decontamination of the digestive tract

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Universitair Medisch Centrum Groningen

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** Cefotaxime, critical care, pharmacokinetics, target attainment

## Outcome measures

### Primary outcome

Total bound and unbound plasma concentrations of cefotaxime; target attainment and maintenance at different time intervals based on a predefined target minimal inhibitory concentration (MIC)

### Secondary outcome

Describing cefotaxime PK parameters

Parameters relevant to pharmacokinetic profile of subjects; including ideal body weight (kgs), actual body weight (kgs), fluid balance (L), creatinine (mg/mL), creatinine clearance (mL/min), derived from creatinine concentration in plasma and a 24-hour aliquot of urine, volume of distribution (total drug dose (mgs) divided by plasma cefotaxime concentration (mg/L)), albumin (mg/mL). To identify relationships between patient characteristics (e.g. APACHE II score, serum albumin concentration, kidney function etc.) and cefotaxime levels that can contribute to optimized dosing in selected patientgroups using multiple regression.

## Study description

### Background summary

Critically ill patients have other pharmacokinetic/pharmacodynamic profiles than healthy volunteers. Suboptimal, both under- and overdosing of antibiotics

is an important threat in this patient category. Given the time-dependent character of beta-lactam antibiotics continuous dosing as opposed to traditional intermittent dosing is likely to render better target attainment and maintenance and might improve clinical outcome.

## **Study objective**

The main objective is to assess target attainment of cefotaxime levels in the critically ill treated with either continuously or intermittently dosed cefotaxime. Secondary objectives are: to develop a predictive mathematical pharmacokinetic (PK) model of cefotaxime in the critically ill; to identify relationships between patient characteristics (e.g. APACHE II score, serum albumin concentration, kidney function etc.) and cefotaxime levels that can contribute to optimized dosing in selected patientgroups using multiple regression.

## **Study design**

Prospective randomized controlled single centre study

## **Study burden and risks**

Patients will be randomized into one of two treatment-arms; one with intermittent dosing; one with continuous dosing. Both intermittent and continuous dosing are currently options in our protocol for routine administration. Blood samples will be drawn on predefined time points after drug administration through an arterial line placed for routine patient management. Maximum amount of blood drawn for this study will be 28 mL (8 samples of 2 mL on day 1; 2 samples of 2 mL on day 2 - 4).

Besides the drawing of blood for cefotaxime blood concentration analysis and anonymous data-collection, in this study patients will not be subjected to any other intervention.

The risks for subjects included in this study are considered to be minor: small volume blood samples are drawn from an indwelling catheter.

No benefits are to be expected for human subjects in this experiment. This study can, however, contribute to optimized dosing of cefotaxime in the critically ill through enhanced knowledge of pharmacokinetics/pharmacodynamics in this specific patient category.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Adult ( $\geq 18$  yrs. of age) patients
- Admitted to intensive care
- Indication for treatment with cefotaxime (as judged by treating physician)

### Exclusion criteria

Renal replacement therapy  
Contraindications for cefotaxime use  
No indication for an arterial line

## Study design

## Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2015
Enrollment:	60
Type:	Actual

## Ethics review

Approved WMO	
Date:	12-06-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

## 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**

NL50809.042.14