Pharmacokinetics of ertapenem in a three-weekly dosing regime in patients with end stage renal disease depending on hemodialysis

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To investigate the Ertapenem plasmaconcentration time curves in a dosingscheme of three administrations per week after hemodialysis in patients with end stage renal disease depending on hemodialysis. To find a pharmacokinetic model to describe...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON34802

Source
ToetsingOnline

Brief title
Pharmacokinetics of ertapenem in hemodialysis patients

Condition

- Bacterial infectious disorders
- Renal disorders (excl nephropathies)

Synonym
End stage renal disease, hemodialysis, infection

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Financiering door instelling waar het onderzoek wordt uitgevoerd

Intervention

Keyword: Ertapenem, Haemodialysis, Pharmacokinetics

Outcome measures

Primary outcome

A pharmacokinetic model which describes the plasma concentration time curves

for Ertapenem.

Secondary outcome

Clinical improvement of the infection

Study description

Background summary

Imipinem-Cilastine (Tienam) is used in the threatment of carbapenem susceptible infections in patients with end-stadium-renal-disease depending on hemodialysis. Of the carbapenems only Imipinem-Cilastine is approved in patients depending on hemodialysis. A disadvantage is the twice daily intravenous injection for which hospitalization is necassary.
Ertapenem (Invanz) is not approved in patients depending on hemodialysis. Based on one pharmacokinetic study a dose reduction of 50% is recommended. Our hypothesis is that an interval increase instead of a dose reduction will also give effective druglevels. In the current daily pratice Ertapenem is already administered three times a week after a hemodialysissession. In this dosageregime no hospitaladmission is needed. In this study we will investigate this dosageregime and descripe the pharmacokinetics in hemodialysis patients.

Study objective

To investigate the Ertapenem plasmaconcentration time curves in a dosingscheme of three administrations per week after hemodialysis in patients with end stage renal disease depending on hemodialysis. To find a pharmacokinetic model to

describe plasma concentration time curves for Ertapenem?

Study design

Single center, multiple-dose, pharmacokinetic study

Intervention

Threatment of the infection with Ertapenem.

Study burden and risks

The risks are minimal. In the current clinical practice patients are treated with this dosageregime of three administration a week after hemodialysis. With this research we try to describe this regime with a pharmacokinetic model. The burden is limited. 6 bloodsamples will be collected, for only 2 samples venapunction is needed. Patients have to stay 30 minutes (administration ertapenem) + 10 minutes (to collect bloodsample) extra in the hospital. A hospitalisation is prevented using this dosageregime.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Hemodialysis patient

Exclusion criteria

- Age < 18
- Liverdisease
- Alcoholabuse
- Allergy for carbapenems
- Diarrhoea
- Use of valproicacid, probenicid
- Pregnancy or lactation

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-12-2010
Enrollment:	8
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Invanz
Generic name:	Ertapenem
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	05-07-2010
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	21-10-2010
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	ID
EudraCT	EUCTR2010-020492-23-NL
CCMO	NL31732.101.10