Pharmacokinetics of anidulafungin in critically ill patients with invasive candidiasis

Published: 02-11-2009
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To investigate the correlation of pharmacokinetic parameters of anidulafungin with markers for disease severity and plasma protein levels.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Fungal infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON32922

Source
ToetsingOnline

Brief title
Pharmacokinetics of anidulafungin

Condition

- Fungal infectious disorders

Synonym
invasive candidiasis, invasive fungal infection

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: anidulafungin, intensive care, invasive candidiasis, pharmacokinetics

Outcome measures

Primary outcome

The primary endpoint is the correlation between pharmacokinetic parameters and disease severity scores or a single clinical parameter. Pharmacokinetic parameters will be calculated out of anidulafungin levels and relevant patient data (i.e. bodyweight, renal function, etc) using KINFIT (MWPharm 3.60; Mediware, The Netherlands). A Spearman correlation coefficient will be calculated to assess correlation as we expect that the results will be not normally distributed.

Secondary outcome

1) Time (in days) to culture conversion

2) Response to treatment at day 28

3) Mortality at day 28 due to fungal infection and overall mortality at 28 days

4) AUC/MIC ratio, time above MIC

5) Composing a pharmacokinetic model of anidulafungin in critically ill patients.

Study description

Background summary

Patients in the ICU are more at risk for the development of invasive candidiasis than patients on other wards. Attributable mortality of candidiasis was evaluated retrospectively between 2003 and 2007 in a hospital in the UK. The crude mortality among ICU case patients was 45.0% compared with 16.7% in

the matched controls; the resulting **attributable mortality** was therefore estimated to be 28.3%.
One of the risk factors for mortality of patients with candidemia is inadequate therapy. So it is important to start antifungal therapy as soon as possible and ensure that adequate levels are reached.
At this moment there are several clues that the pharmacokinetics of anidulafungin in critically ill patients is different, but an overall picture is lacking.

Study objective

To investigate the correlation of pharmacokinetic parameters of anidulafungin with markers for disease severity and plasma protein levels.

Study design

This study is an observational pharmacokinetic study. At day 3 (± 1 day) after start of treatment a full anidulafungin concentration-time curve will be obtained. Blood samples are taken just before administering anidulafungin and at 1.5, 2, 3, 4, 6, 8, 12 and 24 hour after the start of the infusion. Besides, trough levels will be followed longitudinally during treatment with a maximum of 28 days every three days to evaluate potential fluctuations in levels over time.

Study burden and risks

There is no direct benefit for the subjects in this study. Result of this study may however contribute to tailor-made dosing for future patients, but conceivably also for the patients studied for future episodes of illness with suspected invasive fungal infection.
The extra blood samples needed to study the pharmacokinetics are no extra burden as these patients already have an indwelling catheter.
This study can not be conducted without these patients as these are subject of investigation.

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

treatment with anidulafungin
at least 18 years of age
invasive canidiasis
admitted to an intensive care unit

Exclusion criteria

allergic to anidulafungin or its excipients
contra-indication stated in IB1-brochure
neutropenia

Study design

Design

Study phase:	4
Study type:	Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-06-2010
Enrollment:	20
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ecalta
Generic name:	anidulafungin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	02-11-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-01-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-05-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	17-06-2010
Application type:	Amendment
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	ID
EudraCT	EUCTR2009-016386-28-NL
CCMO	NL30035.042.09