Pharmacokinetics of micafungin in critically ill patients with invasive candidiasis.

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Establish the pharmacokinetic parameters of micafungin in critically ill patients and determine whether pharmacokinetic parameters and plasma concentrations of micafungin correlate with disease severity.

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

Summary

ID

NL-OMON37779

Source
ToetsingOnline

Brief title
Pharmacokinetics of micafungin.

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,Astellas Pharma

Intervention

Keyword: Intensive care, Invasive candidiasis, Micafungin, Pharmacokinetics

Outcome measures

Primary outcome

The main study parameter is the correlation of the pharmacokinetic parameters and plasma concentration of micafungin with disease severity scores.

Secondary outcome

1) Pharmacokinetic parameters of micafungin in ICU patients.

2) Time (in days) to culture conversion.

3) Correlation of the plasma concentration of micafungin with response to treatment.

4) Correlation of the plasma concentration of micafungin with inflammation parameters.

5) AUC/MIC ratio and Cmax/MIC ratio.

6) Constructing a pharmacokinetic model of micafungin in critically ill patients.

Study description

Background summary

In adult patients, the overall mortality rate attributable to candidemia varies from 14.5 to 49%. Furthermore, candidemia is associated with an increase in length of hospital stay and hospital charges. Intensive care unit (ICU) patients are especially at risk for invasive candidiasis due to the presence of risk factors. A study of micafungin in ICU versus non-ICU patients showed a significantly lower treatment success in ICU patients (62.5% success) compared with non-ICU patients (85% success). The Acute Physiology and Chronic Health Evaluation II score for disease severity was a potential explanatory factor

associated with treatment success. Furthermore, it is known that in critically ill patients, alterations in function of various organs and body systems influences the pharmacokinetics and hence the plasma concentration of a drug. The pharmacokinetic parameters of micafungin in critically ill patients are most likely different, but this had not been specifically studied.

Study objective

Establish the pharmacokinetic parameters of micafungin in critically ill patients and determine whether pharmacokinetic parameters and plasma concentrations of micafungin correlate with disease severity.

Study design

Observational pharmacokinetic study. On day 4 (± 1 day) of treatment with micafungin, a full pharmacokinetic profile of micafungin will be obtained. Blood samples are taken just before administration of micafungin and 1, 2, 3, 4, 6, 8, 12 and 24 hours after the start of the infusion. Besides, trough levels will be followed every three days during treatment on the ICU, with a maximum of 28 days, to evaluate potential fluctuations in micafungin concentration over time. On the day the full micafungin curve is obtained, blood samples are drawn for determination of procalcitonin, interleukin-6 and interleukin-8 to assess correlation of micafungin plasma concentration with inflammation parameters. Different disease severity scores (APACHE II, APACHE IV, LODS, MODS, MPM II, ODIN, SAPS 3, SOFA) will be calculated on the day the full pharmacokinetic profile of micafungin is obtained. The calculation of the different scores is based on clinical parameters that are routinely recorded for ICU patients.

Study burden and risks

Results of this study can contribute to practical decision rules for therapeutic drug monitoring and future dosing schedules in critically ill patients treated with micafungin. The extra blood samples needed to study the pharmacokinetic parameters are no extra burden as these patients already have an indwelling vascular catheter.
This study cannot be conducted without these patients as they are the 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 micafungin
Admission to an ICU
Age >= 18 years
Invasive candidiasis

Exclusion criteria

Blood sampling not possible.

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):	04-12-2012
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	03-08-2012
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	ID
Other	clinicaltrials.gov
CCMO	NL39246.042.12