Clinical trial results:
PHARMACOKINETICS OF MICAFUNGIN DURING CONTINUOUS VENOVENOUS HEMOFILTRATION

Summary

EudraCT number	2012-000904-14
Trial protocol	AT
Global end of trial date	01 June 2016

Results information

Result version number	v1 (current)
This version publication date	29 May 2020
First version publication date	29 May 2020
Summary attachment (see zip file)	Synopsis (Synopsis Micafungin plasma levels are not affected by continuous renal replacement therapy.pdf)

Trial information

Trial identification

Sponsor protocol code	MICA_HDF

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Spitalgasse 23, Vienna, Austria, 1090
Public contact	Florian Thalhammer, Medizinische Universität Wien, 0043 14040044400, florian.thalhammer@meduniwien.ac.at
Scientific contact	Florian Thalhammer, Medizinische Universität Wien, 0043 14040044400, florian.thalhammer@meduniwien.ac.at

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	12 June 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 June 2015
Global end of trial reached?	Yes
Global end of trial date	01 June 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Measuring pharmakokinetecs of micafungin during continuous renal replacement therapy

Protection of trial subjects:

None necessary (PK sampling using HF machine ports only)

Background therapy:

none

Evidence for comparator:

no comparator

Actual start date of recruitment	27 July 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Austria: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	9
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment started End of June 2013 and concluded December 2014. Patients from all ICUs of the general hospital of vienna were included.

Pre-assignment

Screening details:

Patients receiving Micafungin and high-flow CVVHDF or CVVHD during their ICU stay were screened.

Period 1

Period 1 title	overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

none

Arms

Arm title	Micafungin therapy

Arm description:

PK Parameters from Patients receiving Micafungin were evaluated

Arm type	Experimental
Investigational medicinal product name	Micafungin
Investigational medicinal product code	J02AX05
Other name	Mycamine
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous drip use

Dosage and administration details:

1x100mg

Number of subjects in period 1	Micafungin therapy
Started	10
Completed	7
Not completed	3
Adverse event, serious fatal	1
Physician decision	2

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	10	10	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
56.6 ± 11.4			
Units: years			
geometric mean	56.6		
standard deviation	± 11.4	-	
Gender categorical Units: Subjects			
Female	3	3	
Male	7	7	

End points

End points reporting groups

Reporting group title	Micafungin therapy
Reporting group description: PK Parameters from Patients receiving Micafungin were evaluated	

Primary: Clearance

End point title	Clearance[1]
End point description: Pre-/post Hemofilter Clearance	
End point type	Primary
End point timeframe: 48 hours	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Purely descriptive pharmacokinetic trial, no statistic calculations were performed

End point values	Micafungin therapy			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: ml/min				
arithmetic mean (standard deviation)				
clearance	46.0 (± 21.7)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

48 hours

Adverse event reporting additional description:

Adverse events were assessed by chart review

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	10.0

Reporting groups

Reporting group title	whole trial

Reporting group description:

all subjects

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No Adverse events apart from the two documented SAEs have been found

Serious adverse events	whole trial		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 10 (20.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Vascular disorders			
Haemorrhage	Additional description: The pre-existing leak of the aorta worsened in the earla morning of the 1st of April 2014. As a result the patient had to undergo emergency surgery. The bleeding was found to originate from under a aortal stent and was linked to leaking intraabdomi		
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death	Additional description: Patient was septic when Mycamine treatment was initiated. She did not respond to treatment and her condition deteriorated dramatically. On the 20th of February 2014 the Pt. died. In the post-mortem analysis a toxic megacolon was found		
subjects affected / exposed	1 / 10 (10.00%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	whole trial		
Total subjects affected by non-serious adverse events subjects affected / exposed	0 / 10 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 June 2014	Additional sampling at hour 1, 25 and 49

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/28584142