Clinical trial results:
LUNG PENETRATION OF CASPOFUNGIN INTO EPITHELIAL LINING FLUID

Summary

EudraCT number	2006-004107-20
Trial protocol	AT
Global end of trial date	01 December 2008

Results information

Result version number	v1 (current)
This version publication date	28 January 2023
First version publication date	28 January 2023

Trial information

Trial identification

Sponsor protocol code	CAS ELF

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52, Innsbruck, Austria, 6020
Public contact	Univ.Prof. Dr. Romuald Bellmann, University Hospital for Internal Medicine I , Anichstrasse 35, 6020 Unnsbruck, +43 (0)512 504 23539, romuald.bellmann@tirol-kliniken.at
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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	01 December 2008
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 December 2008
Global end of trial reached?	Yes
Global end of trial date	01 December 2008
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine concentrations of caspofungin in the epithelial lining fluid (ELF) compared to the plasma concentration of caspofungin in patients with fungal infection.

Protection of trial subjects:

N/A

Background therapy:

-

Evidence for comparator:

-

Actual start date of recruitment	24 October 2007
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: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No patients were recruited for this trial. "99999" is a value for 0 participants.

Pre-assignment

Screening details:

N/A

Period 1

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

Arms

Arm title	Caspofungin Acetate
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Caspofungin Acetate
Investigational medicinal product code	
Other name	Cancidas
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

N/A

Number of subjects in period 1	Caspofungin Acetate
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Caspofungin Acetate

Reporting group description: -

Reporting group values	Caspofungin Acetate	Total	
Number of subjects	99999	99999	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Caspofungin Acetate

Reporting group description: -

Primary: Caspofungin Acetate

End point title	Caspofungin Acetate[1]

End point description:

End point type	Primary

End point timeframe:

N/A

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: No patients were enrolled in this trial, therefore no statistical analysis was done.

End point values	Caspofungin Acetate			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: N/A				
number (not applicable)	99999			

Notes:

[2] - "99999" is a value for 0 participants.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 24.10.2007-01.12.2008	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	3.0

Reporting groups	
Reporting group title	Caspofungin Acetate
Reporting group description: -	

Serious adverse events	Caspofungin Acetate		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Caspofungin Acetate		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

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 patients were enrolled in this trial, therefore no AEs or SAEs were observed.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No subjects were enrolled in this trial. "99999" is a value for 0 participants, as it was not possible to fill in "0" for the number of included patients.

Notes: