Clinical trial results:
Concentrations of doripenem in the cerebrospinal fluid of neurointensive care patients with extraventricular drainage due to secondary obstructive hydrocephalus

Summary

EudraCT number	2010-020920-24
Trial protocol	AT
Global end of trial date	31 October 2014

Results information

Result version number	v1 (current)
This version publication date	31 October 2020
First version publication date	31 October 2020

Trial information

Trial identification

Sponsor protocol code	Doripenem–CSF

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medizinische Universität Wien, Univ. Klinik f. Innere Medizin I, Abt. f. Infektionen u. Tropenmedizin
Sponsor organisation address	Waehringer Gürtel 18-20 , Vienna, Austria, 1090
Public contact	Sarah.schwarz@meduniwien.ac.at, 0043 1 4040044405, 0043 1 4040044405, Sarah.schwarz@meduniwien.ac.at
Scientific contact	Sarah.schwarz@meduniwien.ac.at, 0043 1 4040044405, 0043 1 4040044405, Sarah.schwarz@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	31 October 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 October 2013
Global end of trial reached?	Yes
Global end of trial date	31 October 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

to test the ability of doripenem to penetrate into the CSF of neurointensive care patients with extraventricular drainage due to secondary obstructive hydrocephalus

Protection of trial subjects:

Patient were monitored at the ICU

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 May 2011
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: 9
Worldwide total number of subjects	9
EEA total number of subjects	9

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	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients after subarachnoidal hemorrage requiring intensive care and extraventriculardrainage due to secondary obstructive hydrocephalus, and clinical indication for tratment with doripenem.

Pre-assignment

Screening details:

Patients with subarachnoidal hemorrage requiring intensive care and extraventriculardrainage due to secondary obstructive hydrocephalus, and clinical indication for tratment with doripenem at the neurosurgical ICU (General Hospital Vienna)

Period 1

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

Arms

Arm title	Doripenem

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Doripenem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

500 mg

Number of subjects in period 1	Doripenem
Started	9
Completed	9

Baseline characteristics

End points

End points reporting groups

Reporting group title	Doripenem

Reporting group description: -

Primary: The concentration of doripenem in CSF and plasma will be measured.

End point title	The concentration of doripenem in CSF and plasma will be measured.[1]

End point description:

Pharmacokinetic concentration of doripenem in CSF and plasma.

End point type	Primary

End point timeframe:

48h

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: Just one Arm, descriptive design

End point values	Doripenem			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: mg/l				
number (not applicable)	9			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Patients are continuesly monitored at the ICU.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups

Reporting group title	Doripenem

Reporting group description: -

Serious adverse events	Doripenem		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 9 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Doripenem		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 9 (11.11%)		
Infections and infestations			
Infection masked			
subjects affected / exposed	1 / 9 (11.11%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported