



Clinical trial results: MEROPENEM and CIPROFLOXACIN DOSING IN THE CRITICALLY ILL PATIENT WITH SEPTIC SHOCK – A SINGLE CENTER PHARMACOKINETIC STUDY

Summary

EudraCT number	2014-002555-26
Trial protocol	DK
Global end of trial date	31 December 2015

Results information

Result version number	v1 (current)
This version publication date	20 May 2022
First version publication date	20 May 2022
Summary attachment (see zip file)	Results summary MacDIPSS (Abstract MacDIPSS 170417b.pdf) MacDIPSS publication (Sjövall 2017 JAC Meropenem Pop PK.pdf)

Trial information

Trial identification

Sponsor protocol code	RH-RBWH-2014-1
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02240277
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Blegdamsvej 9, Copenhagen, Denmark,
Public contact	Clinical Trials Information, Dept. of Intensive Care Medicine, karl.fredrik.lennart.sjoevall@regionh.dk
Scientific contact	Clinical Trials Information, Dept. of Intensive Care Medicine, karl.fredrik.lennart.sjoevall@regionh.dk

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	09 May 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 December 2015
Global end of trial reached?	Yes
Global end of trial date	31 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate present meropenem and ciprofloxacin dosing and achieved plasma concentrations in relation to bacterial susceptibility in patients with septic shock.

Protection of trial subjects:

Regular patient protection and insurance

Background therapy:

Usual care

Evidence for comparator:

N/A

Actual start date of recruitment	03 November 2014
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	Denmark: 50
Worldwide total number of subjects	50
EEA total number of subjects	50

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)	15
From 65 to 84 years	35
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Pt admitted to the ICU with either meropenem or ciprofloxacin treatment were eligible for testing.

Period 1

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

Arms

Arm title	Rigshospitalet
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Arm description:

Meropenem and ciprofloxacin

Arm type	observational
Investigational medicinal product name	meropenem
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Standard dosing according to treating doctor

Number of subjects in period 1	Rigshospitalet
Started	50
Completed	50

Baseline characteristics

End points

End points reporting groups

Reporting group title	Rigshospitalet
Reporting group description: Meropenem and ciprofloxacin	

Primary: Plasma concentration

End point title	Plasma concentration ^[1]
End point description:	

End point type	Primary
End point timeframe: During the treatment period	

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: Observational study with proportions and montecarlo simulation

End point values	Rigshospitalet			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: g/L				
number (not applicable)	50			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

ASAP

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	1
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Frequency threshold for reporting non-serious adverse events: 1 %

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 non serious adverse events were recorded

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

None reported