Clinical trial results:
Offene, monozentrische, nicht kontrollierte und nicht randomisierte Phase IV-Studie zur Bestimmung der Pharmakokinetik von Carbapenemen in adipösen Patienten.

Summary

EudraCT number	2010-024094-39
Trial protocol	DE
Global end of trial date	01 July 2015

Results information

Result version number	v1
This version publication date	03 April 2021
First version publication date	03 April 2021

Trial information

Trial identification

Sponsor protocol code	Adip-2010

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01407965
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University Hospital Ulm
Sponsor organisation address	Albert-Einstein-Allee 29, Ulm, Germany, 89081
Public contact	Frau Prof. Dr. med. D. Henne-Bruns, Dr. med. M. Wittau, Klinik für Allgemein- und Viszeralchirurgie, 49 731 500 53500, mathias.wittau@uniklinik-ulm.de
Scientific contact	Frau Prof. Dr. med. D. Henne-Bruns, Dr. med. M. Wittau, Klinik für Allgemein- und Viszeralchirurgie, 49 731 500 53500, mathias.wittau@uniklinik-ulm.de

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 July 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 July 2015
Global end of trial reached?	Yes
Global end of trial date	01 July 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to determine the free tissue kinetics of ertapenem and meropenem in fatty tissue and intraperitoneal fluid up to 24 hours after administration of the IMP. Subjects are patients. Hospitalized patients 18 years or older requiring elective surgical intervention (open or laparoscopic surgery) at intraabdominal organs with a BMI >= 40 will be eligible for this study. Further, the free and bound plasma concentration of the IMPs will be determined.

Protection of trial subjects:

N/A

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 June 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	Germany: 13
Worldwide total number of subjects	13
EEA total number of subjects	13

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)	13
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment started on 30-Jun-2011; first patient was enrolled (FPI) on 13-Aug-2012; in total 13 subjects have been recruited, country: Germany

Pre-assignment

Screening details:

N.A.

Pre-assignment period milestones

Number of subjects started	13
Number of subjects completed	13

Period 1

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

Arms

Arm title	active

Arm description:

Meropenem + Ertapenem

Arm type	Experimental
Investigational medicinal product name	Meropenem
Investigational medicinal product code	38592.02.00
Other name	Meronem
Pharmaceutical forms	Infusion
Routes of administration	Intracavernous use

Dosage and administration details:

infusion of 1 g in 100 ml 0.9% sodium chloride over 15 min

Investigational medicinal product name	Ertapenem
Investigational medicinal product code	EU/1/02/216/001 + EU/1/02/216/002
Other name	Invanz
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

infusion of 1 g ertapenem in 100 ml of 0.9% sodium chloride over 15 min

Number of subjects in period 1	active
Started	13
Completed	12
Not completed	1
Physician decision	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial
Reporting group description:	
All subjects	

Reporting group values	Overall trial	Total	
Number of subjects	13	13	
Age categorical			
All subjects			
Units: Subjects			
Adults (18-64 years)	13	13	
Gender categorical Units: Subjects			
Female	10	10	
Male	3	3	

End points

End points reporting groups

Reporting group title	active
Reporting group description:	
Meropenem + Ertapenem	

Primary: Pharmacokinetics

End point title	Pharmacokinetics[1]
End point description:	
semikontinuierliche Messung der Kinetik der freien Konzentration von Ertapenem und Meropenem in Peritonealflüssigkeit, Fettgewebe und Plasma von adipösen Patienten (BMI 40).	
End point type	Primary
End point timeframe:	
up to 24 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: Descriptive analysis of antibiotic concentration

End point values	active			
Subject group type	Reporting group			
Number of subjects analysed	12			
Units: mg/L				
number (not applicable)	12			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: from signing informed consent until discharge of patient	
Assessment type	Systematic

Dictionary used	
Dictionary name	verbatim
Dictionary version	0

Reporting groups	
Reporting group title	Overall
Reporting group description: All patients included	

Serious adverse events	Overall		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Overall		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 13 (7.69%)		
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	1 / 13 (7.69%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 August 2011	G.3. Central Technical Facilities changed
12 August 2013	G1.1 Change in address of PI and trial site; B.1.2.1 Change in name

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported