Clinical trial results:
Daptomycin concentration in drainage fluid and blood samples of ICU patients

Summary

EudraCT number	2015-000125-36
Trial protocol	DE
Global end of trial date	31 March 2019

Results information

Result version number	v1 (current)
This version publication date	23 June 2021
First version publication date	23 June 2021

Trial information

Trial identification

Sponsor protocol code	Dapto

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03004066
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University hospital Tübingen
Sponsor organisation address	Hoppe-Seyler-Str. 3, Tübingen, Germany, 72076
Public contact	Intensive Care Unit 39, University Hospital Tübingen, +49 070712986724, helene.haeberle@med.uni-tuebingen.de
Scientific contact	Intensive Care Unit 39, University Hospital Tübingen, +49 070712986724, helene.haeberle@med.uni-tuebingen.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	Interim
Date of interim/final analysis	22 September 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 March 2019
Global end of trial reached?	Yes
Global end of trial date	31 March 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Pharmakokinetics of Daptomycin in intensive care patients with wound drainage after surgery

Protection of trial subjects:

all subjects received normal postoperative intensive care. No additional measures were necessary

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 July 2015
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: 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)	7
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients receiving LVAD implantation for terminal heart failure

Period 1

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

Blinding implementation details:

not blinded

Arms

Arm title	Daptomycin

Arm description:

All patients received Daptomycin after LVAD implantation according to our internal standards.

Arm type	Experimental
Investigational medicinal product name	Daptomycin
Investigational medicinal product code	J01XX09
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection/infusion
Routes of administration	Infusion

Dosage and administration details:

6mg/kg per day, intravenous infusion

Number of subjects in period 1	Daptomycin
Started	9
Completed	9

Baseline characteristics

End points

End points reporting groups

Reporting group title	Daptomycin
Reporting group description:	
All patients received Daptomycin after LVAD implantation according to our internal standards.	
Subject analysis set title	blood concentrations
Subject analysis set type	Per protocol
Subject analysis set description:	
all patients included into the trial	
Subject analysis set title	drain fluid concentrations
Subject analysis set type	Per protocol
Subject analysis set description:	
all patients included into the trial	

Primary: concentrations

End point title	concentrations[1]
End point description:	
End point type	Primary
End point timeframe:	
day 1 to 3	

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: this trial was designed as a pilot project to determine whether a trial including more subjects could be done and should be planned. only 9 subjects were included into the trial.

End point values	Daptomycin	blood concentrations	drain fluid concentrations	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	9	9	9	
Units: mg/l				
arithmetic mean (standard deviation)	30.2 (± 10.2)	50.8 (± 14.7)	19.9 (± 8.0)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 3 days	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	5

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

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: within the monitored time period no adverse events where reported.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 February 2018	trial timeline was changed from 01.07.2016-01.07.2018 to 01.07.2016-31.03.2019 (end of trial)

Notes:

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.

this small trial included patients with terminal heart disease in need of a LVAD implantation and receiving Daptomycin for 3 days, which is a very small collective to recruit from.

Notes: