



## 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:

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**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:

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**General information about the trial**

Main objective of the trial:

Pharmacokinetics 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:

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**Population of trial subjects**

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**Subjects enrolled per country**

|                                      |            |
|--------------------------------------|------------|
| Country: Number of subjects enrolled | Germany: 9 |
| Worldwide total number of subjects   | 9          |
| EEA total number of subjects         | 9          |

Notes:

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**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

|                                       |            |
|---------------------------------------|------------|
| <b>Number of subjects in period 1</b> | Daptomycin |
| Started                               | 9          |
| Completed                             | 9          |

## Baseline characteristics

## End points

### End points reporting groups

|   |                            |
|---|----------------------------|
| Reporting group title   | Daptomycin                 |
| Reporting group description:<br>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:<br>all patients included into the trial   |                            |
| Subject analysis set title  | drain fluid concentrations |
| Subject analysis set type   | Per protocol               |
| Subject analysis set description:<br>all patients included into the trial   |                            |

### Primary: concentrations

|                                    |                               |
|------------------------------------|-------------------------------|
| End point title                    | concentrations <sup>[1]</sup> |
| End point description:             |                               |
| End point type                     | Primary                       |
| End point timeframe:<br>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

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### Adverse events information<sup>[1]</sup>

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Timeframe for reporting adverse events:

3 days

|                 |                |
|-----------------|----------------|
| Assessment type | Non-systematic |
|-----------------|----------------|

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### Dictionary used

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|                 |       |
|-----------------|-------|
| Dictionary name | CTCAE |
|-----------------|-------|

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|                    |   |
|--------------------|---|
| Dictionary version | 5 |
|--------------------|---|

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

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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 were 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:

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### 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.

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|--|
| 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. |
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Notes: