



Clinical trial results: PHARMACOKINETICS OF MICAFUNGIN DURING CONTINUOUS VENOVENOUS HEMOFILTRATION

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2012-000904-14 |
| Trial protocol | AT |
| Global end of trial date | 01 June 2016 |

Results information

| | |
|-----------------------------------|---|
| Result version number | v1 (current) |
| This version publication date | 29 May 2020 |
| First version publication date | 29 May 2020 |
| Summary attachment (see zip file) | Synopsis (Synopsis Micafungin plasma levels are not affected by continuous renal replacement therapy.pdf) |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | MICA_HDF |
|-----------------------|----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Medical University of Vienna |
| Sponsor organisation address | Spitalgasse 23, Vienna, Austria, 1090 |
| Public contact | Florian Thalhammer, Medizinische Universität Wien, 0043 14040044400, florian.thalhammer@meduniwien.ac.at |
| Scientific contact | Florian Thalhammer, Medizinische Universität Wien, 0043 14040044400, florian.thalhammer@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 | 12 June 2017 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 18 June 2015 |
| Global end of trial reached? | Yes |
| Global end of trial date | 01 June 2016 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

Measuring pharmacokinetics of micafungin during continuous renal replacement therapy

Protection of trial subjects:

None necessary (PK sampling using HF machine ports only)

Background therapy:

none

Evidence for comparator:

no comparator

| | |
|---|--------------|
| Actual start date of recruitment | 27 July 2012 |
| 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: 10 |
| Worldwide total number of subjects | 10 |
| EEA total number of subjects | 10 |

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 | 1 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

Recruitment started End of June 2013 and concluded December 2014. Patients from all ICUs of the general hospital of vienna were included.

Pre-assignment

Screening details:

Patients receiving Micafungin and high-flow CVVHDF or CVVHD during their ICU stay were screened.

Period 1

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

Blinding implementation details:

none

Arms

| | |
|-----------|--------------------|
| Arm title | Micafungin therapy |
|-----------|--------------------|

Arm description:

PK Parameters from Patients receiving Micafungin were evaluated

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | Micafungin |
| Investigational medicinal product code | J02AX05 |
| Other name | Mycamine |
| Pharmaceutical forms | Concentrate and solvent for solution for infusion |
| Routes of administration | Intravenous drip use |

Dosage and administration details:

1x100mg

| Number of subjects in period 1 | Micafungin therapy |
|--------------------------------|--------------------|
| Started | 10 |
| Completed | 7 |
| Not completed | 3 |
| Adverse event, serious fatal | 1 |
| Physician decision | 2 |

Baseline characteristics

Reporting groups

| | |
|-----------------------|---------------|
| Reporting group title | overall trial |
|-----------------------|---------------|

Reporting group description: -

| Reporting group values | overall trial | Total | |
|---|---------------|-------|--|
| Number of subjects | 10 | 10 | |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | | 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) | | 0 | |
| From 65-84 years | | 0 | |
| 85 years and over | | 0 | |
| Age continuous | | | |
| 56.6 ± 11.4 | | | |
| Units: years | | | |
| geometric mean | 56.6 | | |
| standard deviation | ± 11.4 | - | |
| Gender categorical | | | |
| Units: Subjects | | | |
| Female | 3 | 3 | |
| Male | 7 | 7 | |

End points

End points reporting groups

| | |
|---|--------------------|
| Reporting group title | Micafungin therapy |
| Reporting group description: | |
| PK Parameters from Patients receiving Micafungin were evaluated | |

Primary: Clearance

| | |
|--------------------------------|--------------------------|
| End point title | Clearance ^[1] |
| End point description: | |
| Pre-/post Hemofilter Clearance | |
| End point type | Primary |
| End point timeframe: | |
| 48 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: Purely descriptive pharmacokinetic trial, no statistic calculations were performed

| End point values | Micafungin therapy | | | |
|--------------------------------------|--------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 7 | | | |
| Units: ml/min | | | | |
| arithmetic mean (standard deviation) | | | | |
| clearance | 46.0 (± 21.7) | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

48 hours

Adverse event reporting additional description:

Adverse events were assessed by chart review

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 10.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|-------------|
| Reporting group title | whole trial |
|-----------------------|-------------|

Reporting group description:

all subjects

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 Adverse events apart from the two documented SAEs have been found

| Serious adverse events | whole trial | | |
|--|--|--|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | |
| number of deaths (all causes) | 1 | | |
| number of deaths resulting from adverse events | 1 | | |
| Vascular disorders | | | |
| Haemorrhage | Additional description: The pre-existing leak of the aorta worsened in the early morning of the 1st of April 2014. As a result the patient had to undergo emergency surgery. The bleeding was found to originate from under a aortal stent and was linked to leaking intraabdomi | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 0 | | |
| General disorders and administration site conditions | | | |
| Death | Additional description: Patient was septic when Mycamine treatment was initiated. She did not respond to treatment and her condition deteriorated dramatically. On the 20th of February 2014 the Pt. died. In the post-mortem analysis a toxic megacolon was found | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| occurrences causally related to treatment / all | 0 / 1 | | |
| deaths causally related to treatment / all | 0 / 1 | | |

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

| | | | |
|---|----------------|--|--|
| Non-serious adverse events | whole trial | | |
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|--------------|--|
| 16 June 2014 | Additional sampling at hour 1, 25 and 49 |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/28584142>