



Clinical trial results: Gastrointestinal behavior of atazanavir in healthy volunteers Summary

| | |
|--------------------------|------------------|
| EudraCT number | 2017-004579-29 |
| Trial protocol | BE |
| Global end of trial date | 20 February 2020 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 02 May 2020 |
| First version publication date | 02 May 2020 |
| Summary attachment (see zip file) | Atazanavir-Hens-2020 (Hens et al. - atazanavir - 2020.pdf) |

Trial information

Trial identification

| | |
|-----------------------|----------|
| Sponsor protocol code | DDD17ATZ |
|-----------------------|----------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | KU Leuven |
| Sponsor organisation address | Herestraat 49, Leuven, Belgium, 3000 |
| Public contact | Patrick Augustijns, KU Leuven, 0032 16330301, patrick.augustijns@kuleuven.be |
| Scientific contact | Patrick Augustijns, KU Leuven, 0032 16330301, patrick.augustijns@kuleuven.be |

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 | 20 February 2020 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 20 February 2020 |
| Global end of trial reached? | Yes |
| Global end of trial date | 20 February 2020 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The study aims to investigate principles of supersaturation and precipitation of a weakly basic drug atazanavir along the gastrointestinal tract in healthy human volunteers. The influence of acidic and calory-containing beverages will also be investigated.

Protection of trial subjects:

NA; no stress or pain was examined for the subjects during this trial.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 01 April 2018 |
| 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 | Belgium: 15 |
| Worldwide total number of subjects | 15 |
| EEA total number of subjects | 15 |

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 | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

performed with three experimental conditions. Three women and two men participated in this study, aged between 24 and 49 years old. Exclusion criteria (i.e., GI disorders, infection with hepatitis B, hepatitis C or HIV, use of medication, pregnancy and frequent X-ray exposure) were checked during a medical examination. All volunteers provided

Period 1

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

Arms

| | |
|------------------------------|-------|
| Are arms mutually exclusive? | Yes |
| Arm title | water |

Arm description:

atazanavir was given with a glass of water

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | Atazanavir |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

one capsule of atazanavir was given with a glass of water

| | |
|------------------|---------------|
| Arm title | PPI condition |
|------------------|---------------|

Arm description:

atazanavir was given under achlorhydric conditions

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | Atazanavir |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

one capsule of atazanavir was given with a glass of water

| | |
|--|--------------|
| Investigational medicinal product name | esomeprazole |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

esomeprazole was given 3 days before the start of the study on each day.

| | |
|------------------|-----------|
| Arm title | Coca Cola |
|------------------|-----------|

Arm description:

Atazanavir was given with a glass of Coca Cola

| | |
|--|--------------|
| Arm type | Experimental |
| Investigational medicinal product name | Atazanavir |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Capsule |
| Routes of administration | Oral use |

Dosage and administration details:

one capsule of atazanavir was given with a glass of coca cola

| Number of subjects in period 1 | water | PPI condition | Coca Cola |
|---------------------------------------|-------|---------------|-----------|
| Started | 5 | 5 | 5 |
| Completed | 5 | 5 | 5 |

Baseline characteristics

End points

End points reporting groups

| | |
|--|---------------|
| Reporting group title | water |
| Reporting group description: atazanavir was given with a glass of water | |
| Reporting group title | PPI condition |
| Reporting group description: atazanavir was given under achlorhydric conditions | |
| Reporting group title | Coca Cola |
| Reporting group description: Atazanavir was given with a glass of Coca Cola | |

Primary: GI and plasma AUC, Cmax and Tmax

| | |
|--|----------------------------------|
| End point title | GI and plasma AUC, Cmax and Tmax |
| End point description: | |
| End point type | Primary |
| End point timeframe: The intake of the capsule was done randomly and not during a specific phase of the MMC cycle. After administration, antral and duodenal fluids were aspirated for 4 h; samples were taken each 15 min. | |

| End point values | water | PPI condition | Coca Cola | |
|-----------------------------|-----------------|-----------------|-----------------|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 5 | 5 | 5 | |
| Units: Concentration | | | | |
| number (not applicable) | 5 | 5 | 5 | |

Statistical analyses

| | |
|---|--|
| Statistical analysis title | Data Presentation and Statistical Analysis |
| Comparison groups | water v PPI condition v Coca Cola |
| Number of subjects included in analysis | 15 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | < 0.05 |
| Method | ANOVA |
| Parameter estimate | Mean difference (final values) |

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

before, during or after the study, adverse events can be reported

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

Dictionary used

| | |
|-----------------|------------|
| Dictionary name | Excel file |
|-----------------|------------|

| | |
|--------------------|------------|
| Dictionary version | office 365 |
|--------------------|------------|

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: no adverse events were reported. This is not applicable for our study

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