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 investigatie 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