Clinical trial results:
Impact of stomach motility on the gastrointestinal behavior of fosamprenavir in healthy volunteers

Summary

EudraCT number	2016-005043-16
Trial protocol	BE
Global end of trial date	29 January 2019

Results information

Result version number	v1 (current)
This version publication date	01 April 2023
First version publication date	01 April 2023

Trial information

Trial identification

Sponsor protocol code	DDD17FPV

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Clinical Trial Center UZ Leuven: S59932

Notes:

Sponsors

Sponsor organisation name	UZLeuven
Sponsor organisation address	Herestraat, Leuven, Belgium, 3000
Public contact	Patrick Augustijns, KU Leuven, +32 16330301, patrick.augustijns@kuleuven.be
Scientific contact	Patrick Augustijns, KU Leuven, +32 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	05 June 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 January 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the impact of gastric motility on the gastrointestinal behavior of a fosamprenavir tablet in healthy volunteers and its implications for systemic drug exposure

Protection of trial subjects:

xylocaine spray/gel during positioning and removal of nasogastric catheter

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 September 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: 7
Worldwide total number of subjects	7
EEA total number of subjects	7

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	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Only Healthy volunteers were recruited.
Main exclusion criteria:
(potential) pregnancy
history of gastrointestinal pathology and/or illness at the time of the study.

Pre-assignment

Screening details:

Healthy volunteers

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Telzir in MMC phase 1

Arm description:

Oral administration of one tablet of Telzir (700 mg fosamprenavir calcium) with 240 mL of tap water during MMC phase I (i.e. absence of contractions).

Arm type	Experimental
Investigational medicinal product name	fosamprenavir calcium
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral administration of one tablet of Telzir (700 mg fosamprenavir calcium) with 240 mL of tap water during MMC phase I (i.e. absence of contractions).

Arm title	Telzir in MMC phase 2

Arm description:

Oral administration of one tablet of Telzir (700 mg fosamprenavir calcium) with 240 mL of tap water during MMC phase II (i.e. period of gastric contractions).

Arm type	Experimental
Investigational medicinal product name	fosamprenavir calcium
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral administration of one tablet of Telzir (700 mg fosamprenavir calcium) with 240 mL of tap water during MMC phase II (i.e. period of gastric contractions).

Number of subjects in period 1	Telzir in MMC phase 1	Telzir in MMC phase 2
Started	7	7
Completed	7	7

Baseline characteristics

Reporting groups	
Reporting group title	overall study

Reporting group description: -

Reporting group values	overall study	Total	
Number of subjects	7	7	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	7	7	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	5	5	
Male	2	2	

End points

End points reporting groups

Reporting group title	Telzir in MMC phase 1

Reporting group description:

Oral administration of one tablet of Telzir (700 mg fosamprenavir calcium) with 240 mL of tap water during MMC phase I (i.e. absence of contractions).

Reporting group title	Telzir in MMC phase 2

Reporting group description:

Oral administration of one tablet of Telzir (700 mg fosamprenavir calcium) with 240 mL of tap water during MMC phase II (i.e. period of gastric contractions).

Primary: not applicable

End point title	not applicable[1]

End point description:

Since we only conduct exploratory studies in a limited number of volunteers, statistical hypothesis testing is not applicable

End point type	Primary

End point timeframe:

not applicable

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: Since we only conduct exploratory studies in a limited number of volunteers, statistical hypothesis testing is not applicable

End point values	Telzir in MMC phase 1	Telzir in MMC phase 2		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5[2]	6[3]		
Units: NA	5	6		

Notes:

[2] - data from 2 HV were excluded (problem with catheter + problem with difference between MMC1 and MMC2)
[3] - In one participant, the different MMC phases could not be clearly distinguished from each other

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

For each individual, corresponds to timeframe of study participation (from signing of informed consent until last visit).

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23

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: There were no adverse events during the trial

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Since we only conduct exploratory studies in a limited number of volunteers, statistical hypothesis testing is not applicable

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/31682976