



Clinical trial results:

The gastrointestinal behavior of Aprepitant in healthy volunteers

Summary

EudraCT number	2016-001156-22
Trial protocol	BE
Global end of trial date	16 October 2016

Results information

Result version number	v1 (current)
This version publication date	10 June 2020
First version publication date	10 June 2020

Trial information

Trial identification

Sponsor protocol code	DDD16APREPITANT
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Clinical Trial Center UZ Leuven identifier: S59294

Notes:

Sponsors

Sponsor organisation name	KU Leuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	Drug Delivery and Disposition, KU Leuven, +32 16330302, bart.hens@kuleuven.be
Scientific contact	Drug Delivery and Disposition, KU Leuven, +32 16330302, bart.hens@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	12 October 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 October 2016
Global end of trial reached?	Yes
Global end of trial date	16 October 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study the gastrointestinal behavior of aprepitant in healthy volunteers in fasted and fed state

Protection of trial subjects:

No specific measures were taken to protect trial subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 August 2016
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: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

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)	1
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

volunteers were excluded when positive tested for HIV, Hepatitis B/C, gastrointestinal disorders.

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:

NA

Arms

Arm title	Fasted state conditions
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Arm description:

Aprepitant (Emend) was given with a glass of water

Arm type	Experimental
Investigational medicinal product name	Aprepitant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, hard
Routes of administration	Oral use

Dosage and administration details:

Orally dosed with a glass of water

Number of subjects in period 1	Fasted state conditions
Started	1
Completed	1

Baseline characteristics

End points

End points reporting groups

Reporting group title	Fasted state conditions
Reporting group description: Aprepitant (Emend) was given with a glass of water	

Primary: GI and plasma AUC, Cmax and Tmax

End point title	GI and plasma AUC, Cmax and Tmax ^[1]
End point description:	

End point type	Primary
End point timeframe: aspiration for 0-4h together with blood sampling	

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: No statistical analyses were performed.

End point values	Fasted state conditions			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: micromolar				
number (not applicable)	1			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

During the entire study period.

Assessment type	Systematic
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Dictionary used

Dictionary name	Excel file
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Dictionary version	office 365
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Frequency threshold for reporting non-serious adverse events: 0 %

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 AE were reported.

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