



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

EudraCT number	2013-005594-51
Trial protocol	BE
Global end of trial date	24 August 2015

Results information

Result version number	v1 (current)
This version publication date	12 October 2023
First version publication date	12 October 2023

Trial information

Trial identification

Sponsor protocol code	FTB14-ABA01
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Clinical Trail Center: s00000

Notes:

Sponsors

Sponsor organisation name	KU Leuven Drug delivery & Disposition
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	Drug Delivery and Disposition, KU Leuven, 32 16379505, patick.augustijns@kuleuven.be
Scientific contact	Drug Delivery and Disposition, KU Leuven, 32 16379505, patick.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	15 October 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	24 August 2015
Global end of trial reached?	Yes
Global end of trial date	24 August 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the gastrointestinal behavior and absorption of abirateronacetate.

Protection of trial subjects:

xylocaine spray/gel during positioning and removal of nasogastric catheter

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 July 2014
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:

healthy males

Pre-assignment

Screening details:

healthy males

Period 1

Period 1 title	intraluminal behavior abiraterone (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	only fasted state

Arm description: -

Arm type	Experimental
Investigational medicinal product name	abiraterone acetate (zytiga)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

After a fasting period of 12 h a tablet of 250 mg abiraterone acetate (ZYTIGA, Janssen-Cilag International NV) was administered orally with 250 ml of water to the volunteers.

Arm title	fasted and fed state
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	abiraterone acetate (zytiga)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

After a fasting period of 12 h a tablet of 250 mg abiraterone acetate (ZYTIGA, Janssen-Cilag International NV) was administered orally with 250 ml of water to the volunteers.

For the experiments in the fed state, 400 mL of Ensure Plus Vanilla® was administered 20 min before intake of the abiraterone acetate tablet with 250-mL water. Ensure Plus Vanilla® was used to simulate a standard meal.

Number of subjects in period 1	only fasted state	fasted and fed state
Started	4	3
Completed	4	3

Baseline characteristics

Reporting groups

Reporting group title	only fasted state
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Reporting group description: -

Reporting group title	fasted and fed state
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Reporting group description: -

Reporting group values	only fasted state	fasted and fed state	Total
Number of subjects	4	3	7
Age categorical			
healthy males			
Units: Subjects			
Adults (18-64 years)	4	3	7
Gender categorical			
only male healthy volunteers could participate			
Units: Subjects			
Female	0	0	0
Male	4	3	7

End points

End points reporting groups

Reporting group title	only fasted state
Reporting group description: -	
Reporting group title	fasted and fed state
Reporting group description: -	

Primary: concentration of abiraterone acetate

End point title	concentration of abiraterone acetate ^[1]
End point description:	

End point type	Primary
End point timeframe:	
concentration of abiraterone acetate was measured during 4 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: Since we only conduct exploratory studies in a limited number of volunteers, statistical hypothesis testing is not applicable

End point values	only fasted state	fasted and fed state		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3 ^[2]	3		
Units: concentration	0	0		

Notes:

[2] - data from 1 subject could not be used

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
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23
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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 during this 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

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/25592324>

<http://www.ncbi.nlm.nih.gov/pubmed/27061460>