Clinical trial results:
Gastrointestinal behavior of itraconazole in healthy volunteers

Summary

EudraCT number	2011-005928-17
Trial protocol	BE
Global end of trial date	04 May 2016

Results information

Result version number	v1 (current)
This version publication date	28 April 2021
First version publication date	28 April 2021

Trial information

Trial identification

Sponsor protocol code	FTB-11-ITRA01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Pharmacotechnology and Biopharmacy
Sponsor organisation address	Herestraat 49, Leuven, Belgium,
Public contact	Pharmacotechnology and Biopharmacy, Katholieke Universiteit Leuven, 32 16330300, joachim.brouwers@pharm.kuleuven.be
Scientific contact	Pharmacotechnology and Biopharmacy, Katholieke Universiteit Leuven, 32 16330300, joachim.brouwers@pharm.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	13 April 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 May 2016
Global end of trial reached?	Yes
Global end of trial date	04 May 2016
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 itraconazole.

Protection of trial subjects:

Identification of the trial subjects was replaced by study participant numbers.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 April 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: 5
Worldwide total number of subjects	5
EEA total number of subjects	5

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)	5
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Healthy volunteers will be selected via a database that is available in the lab and via mouth to mouth recruitment.

Pre-assignment

Screening details:

xclusion criteria for participation were a history ofgastrointestinal disease(s), pregnancy, frequent exposure toionizing radiation during the previous year, and/or illness at thetime of the study.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	No
Arm title	2 Sporanox capsules

Arm description:

2 Sporanox capsules

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

Dosage and administration details:

200mg of itraconazole administerd in 2 Sporanox capsules

Arm title	20 mL Sporanox oral solution

Arm description:

20 mL Sporanox oral solution

Arm type	Active comparator
Investigational medicinal product name	itraconazole
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral/rectal solution
Routes of administration	Oral use

Dosage and administration details:

200 mg of itraconazole administered via a 20 mL Sporanox oral solution

Number of subjects in period 1	2 Sporanox capsules	20 mL Sporanox oral solution
Started	5	5
Completed	5	5

Baseline characteristics

Reporting groups

Reporting group title	Overall trial (overall period)

Reporting group description: -

Reporting group values	Overall trial (overall period)	Total	
Number of subjects	5	5	
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)	5	5	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
median	25		
full range (min-max)	23 to 27	-	
Gender categorical Units: Subjects			
Female	3	3	
Male	2	2	

End points

End points reporting groups

Reporting group title	2 Sporanox capsules
Reporting group description:	
2 Sporanox capsules	
Reporting group title	20 mL Sporanox oral solution
Reporting group description:	
20 mL Sporanox oral solution	
Subject analysis set title	Sporanox capsules vs solution
Subject analysis set type	Full analysis
Subject analysis set description:	
5 HV who received 200mg of itraconazole delivered one time as 2 sporanox capsules and one time as a 20mL sporanox solution	

Primary: AUC

End point title	AUC[1]
End point description:	
End point type	Primary
End point timeframe:	
from drug administration until 8 hours after administraion	

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 p-value available in the article. Only the mean +- SD was mentioned.

End point values	2 Sporanox capsules	20 mL Sporanox oral solution		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	5	5		
Units: nM x h				
arithmetic mean (standard deviation)	1880 (± 543)	5708 (± 1006)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: From start of visit 1 until the end of visit 2	
Assessment type	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: No adverse events happen in 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

None reported