Clinical trial results:
Gastrointestinal behavior of simvastatin in healthy volunteers

Summary

EudraCT number	2013-001715-76
Trial protocol	BE
Global end of trial date	16 October 2014

Results information

Result version number	v1 (current)
This version publication date	23 May 2020
First version publication date	23 May 2020
Summary attachment (see zip file)	Geboers- simvastatin (Geboers - Simvastatine.pdf)

Trial information

Trial identification

Sponsor protocol code	FTB13-SMV01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Clinical Trail Center: s55581

Notes:

Sponsors

Sponsor organisation name	KU Leuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	Drug Delivery and Disposition, KU Leuven, 32 16330301, sophie.geboers@pharm.kuleuven.be
Scientific contact	Drug Delivery and Disposition, KU Leuven, 32 16330301, sophie.geboers@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	01 April 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 April 2013
Global end of trial reached?	Yes
Global end of trial date	16 October 2014
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 simvastatin.

Protection of trial subjects:

No specific measures were taken to protect the trial subjects.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 March 2013
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: -

Pre-assignment

Screening details:

NA

Period 1

Period 1 title	water condition (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

Arm description:

administering simvastatine in fasted state conditions

Arm type	Placebo
Investigational medicinal product name	Simvastatin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

A single tablet of Zocor (simvastatin, 40 mg) was administered together with 250 mL of water.

Number of subjects in period 1	Fasted state conditions
Started	5
Completed	5

Baseline characteristics

Reporting groups	
Reporting group title	Fasted state conditions
Reporting group description: administering simvastatine in fasted state conditions	

Reporting group values	Fasted state conditions	Total	
Number of subjects	5	5	
Age categorical			
22-26yo			
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	
Gender categorical Units: Subjects			
Female	3	3	
Male	2	2	

Subject analysis sets	
Subject analysis set title	subject analysis set
Subject analysis set type	Full analysis
Subject analysis set description: descriptive statistics (mean+ SD)	

Reporting group values	subject analysis set		
Number of subjects	5		
Age categorical			
22-26yo			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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 65-84 years	0		

85 years and over	0		

Gender categorical Units: Subjects			
Female	3		
Male	2		

End points

End points reporting groups	
Reporting group title	Fasted state conditions
Reporting group description: administering simvastatine in fasted state conditions	
Subject analysis set title	subject analysis set
Subject analysis set type	Full analysis
Subject analysis set description: descriptive statistics (mean+ SD)	

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: 4 hour timeframe	

End point values	Fasted state conditions	subject analysis set		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	5	5		
Units: concentrations				
geometric mean (standard deviation)	23 (± 2)	23 (± 2)		

Statistical analyses

Statistical analysis title	Data Presentation and Statistical Analysis
Comparison groups	Fasted state conditions v subject analysis set
Number of subjects included in analysis	10
Analysis specification	Post-hoc
Analysis type	equivalence
P-value	< 0.05
Method	ANOVA

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: before and after the study. No AE were reported.	
Assessment type	Systematic

Dictionary used	
Dictionary name	Excel file
Dictionary version	office 365

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

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

NA

Notes: