



Clinical trial results:

Effect of citalopram on fasting and postprandial lower esophageal sphincter function in healthy subjects: a double-blind, placebo-controlled, randomized, cross-over study

Summary

EudraCT number	2016-000563-16
Trial protocol	BE
Global end of trial date	07 May 2018

Results information

Result version number	v1 (current)
This version publication date	06 February 2021
First version publication date	06 February 2021
Summary attachment (see zip file)	Article citalopram on LES (Artikel citalopram on LES.pdf)

Trial information

Trial identification

Sponsor protocol code	Citalopram2016
-----------------------	----------------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03746691
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	TARGID
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	TARGID, TARGID, 32 16344225, jan.tack@kuleuven.be
Scientific contact	TARGID, TARGID, 32 16344225, jan.tack@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	04 December 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 May 2018
Global end of trial reached?	Yes
Global end of trial date	07 May 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effect of citalopram on fasting and postprandial lower esophageal sphincter function in healthy subjects

Protection of trial subjects:

Subject identification was replaced by identification number.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 March 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: 16
Worldwide total number of subjects	16
EEA total number of subjects	16

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)	16
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Healthy volunteers were recruited for this study.

Pre-assignment

Screening details:

Healthy volunteers were recruited for this study.

Period 1

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

Arms

Are arms mutually exclusive?	No
------------------------------	----

Arm title	Citalopram
------------------	------------

Arm description:

20 mg of citalopram (0.5 mL) (Cipramil, Lundbeck) or placebo (0.5 ml saline) was administered intravenously over 30 min, using 100 mL saline 0.9% NaCl as vector

Arm type	Experimental
Investigational medicinal product name	Citalopram
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

20 mg of citalopram (0.5 mL) (Cipramil, Lundbeck) or placebo (0.5 ml saline) was administered iv over 30 min, using 100 mL saline 0.9% NaCl as vector

Arm title	Placebo
------------------	---------

Arm description:

Following a 10min stabilization placebo (0.5 ml saline) was administered intravenous over 30 min, using 100 mL saline 0.9% NaCl as vector

Arm type	Placebo
Investigational medicinal product name	Saline solution
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Following a 10min stabilization period after the placement of the catheter, placebo (0.5 ml saline) was administered iv over 30 min, using 100 mL saline 0.9% NaCl as vector

Number of subjects in period 1	Citalopram	Placebo
Started	16	16
Completed	16	16

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	16	16	
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)	16	16	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	23.9		
standard deviation	± 0.39	-	
Gender categorical			
Units: Subjects			
Female	8	8	
Male	8	8	

End points

End points reporting groups

Reporting group title	Citalopram
Reporting group description: 20 mg of citalopram (0.5 mL) (Cipramil, Lundbeck) or placebo (0.5 ml saline) was administered intravenously over 30 min, using 100 mL saline 0.9% NaCl as vector	
Reporting group title	Placebo
Reporting group description: Following a 10min stabilization placebo (0.5 ml saline) was administered intravenous over 30 min, using 100 mL saline 0.9% NaCl as vector	

Primary: Change in LES pressure

End point title	Change in LES pressure
End point description:	
End point type	Primary
End point timeframe:	
Comparison of two conditions	

End point values	Citalopram	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	16		
Units: mmHg				
arithmetic mean (standard error)	14.1 (± 1.6)	11.8 (± 1.2)		

Statistical analyses

Statistical analysis title	Paired t test for LES pressure
Comparison groups	Placebo v Citalopram
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.01
Method	t-test, 2-sided

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From signing informed content until the end of the last study 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: Headache, hunger and nausea was reported during this study. However these symptoms are due to the fact that the subjects needed to be fasted for this study and not due to the administration of citalopram, since these symptoms are both present in the placebo and the citalopram arm.

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