Clinical trial results:
The effect of chlorpromazine (Largactil), a dopamine type 2-(D2-) receptor antagonist, on esophageal sensitivity in healthy volunteers: a randomized, double-blind, placebo-controlled study

Summary

EudraCT number	2016-003131-38
Trial protocol	BE
Global end of trial date	19 October 2017

Results information

Result version number	v1 (current)
This version publication date	07 February 2021
First version publication date	07 February 2021
Summary attachment (see zip file)	Thesis manuscript (Manuscript containing results S60403.pdf)

Trial information

Trial identification

Sponsor protocol code	DOPA2016

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	TARGID
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	TARGID, TARGID, KU Leuven, 32 16344225, jan.tack@kuleuven.be
Scientific contact	TARGID, TARGID, KU Leuven, 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	20 November 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 June 2017
Global end of trial reached?	Yes
Global end of trial date	19 October 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effect of chlorpromazine (Largactil) on esophageal sensitivity in healthy subjects

Protection of trial subjects:

Identification of trial subjects was protected by the implementation of subject numbers

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2017
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: 13
Worldwide total number of subjects	13
EEA total number of subjects	13

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)	13
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

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	Chlorpromazine

Arm description: -

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

Dosage and administration details:

Ten mg chlorpromazine for IV infusion was added to 100mL NaCl 0.9%, infusion ran over 30 minutes.

Arm title	Placebo

Arm description: -

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:

100mL NaCl 0.9%, infusion ran over 30 minutes.

Number of subjects in period 1	Chlorpromazine	Placebo
Started	13	13
Completed	13	13

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	13	13	
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)	13	13	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	25		
full range (min-max)	19 to 40	-	
Gender categorical Units: Subjects			
Female	6	6	
Male	7	7	

End points

End points reporting groups

Reporting group title	Chlorpromazine
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Change in mechanical stimulation

End point title	Change in mechanical stimulation
End point description:	
End point type	Primary
End point timeframe: Between the two conditions	

End point values	Chlorpromazine	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	13		
Units: mL				
median (inter-quartile range (Q1-Q3))	19.15 (17.9 to 25.65)	24.33 (21.8 to 28.35)		

Statistical analyses

Statistical analysis title	Paired t test for mechnical stimulation
Comparison groups	Chlorpromazine v Placebo
Number of subjects included in analysis	26
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.53
Method	t-test, 2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: From signing the informed consent until the end of the last study visit.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23

Reporting groups	
Reporting group title	Chlorpromazine

Reporting group description: -

Serious adverse events	Chlorpromazine		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Chlorpromazine		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 13 (61.54%)		
Nervous system disorders			
Drowsiness			
subjects affected / exposed	3 / 13 (23.08%)		
occurrences (all)	3		
Feeling of being tired			
subjects affected / exposed	5 / 13 (38.46%)		
occurrences (all)	5		

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