Clinical trial results:
THE RELATIONSHIP BETWEEN GASTRIC MOTILITY AND EMPTYING AS MEASURED WITH AN INTRAGASTRIC BALLOON AND BREATH TESTING

Summary

EudraCT number	2016-002889-32
Trial protocol	BE
Global end of trial date	15 March 2017

Results information

Result version number	v1 (current)
This version publication date	14 February 2021
First version publication date	14 February 2021

Trial information

Trial identification

Sponsor protocol code	CodeineII

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	KULeuven UZLeuven
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	TARGID, KU Leuven, 32 163474425, pieter.janssen@kuleuven.be
Scientific contact	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	24 April 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 March 2017
Global end of trial reached?	Yes
Global end of trial date	15 March 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

to investigate the relation between gastric motility and gastric emptying in healthy control volunteers (codeine vs. placebo).

Protection of trial subjects:

Not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 August 2016
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: 6
Worldwide total number of subjects	6
EEA total number of subjects	6

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)	6
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

healty volunteers were recruited

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	20 ml balloon + codeine

Arm description:

20 ml balloon + 60 mg codeine

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

Dosage and administration details:

Codeine was administrated as a syrup: Bronchodine® 10mg 5ml-1. dose 60 mg codein = 30 ml bronchodine syrup was administered

Arm title	200 ml balloon + codeine

Arm description:

200 ml balloon + 60 mg codeine

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

Dosage and administration details:

Codeine was administrated as a syrup: Bronchodine® 10mg 5ml-1. dose 60 mg codein = 30 ml bronchodine syrup was administered

Arm title	20 ml balloon + placebo

Arm description:

20 ml balloon + placebo

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

Dosage and administration details:

30 ml of a homeopathic syrup was administrated (Drosetux)

Arm title	200 ml balloon + placebo

Arm description:

200 ml balloon + placebo

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

Dosage and administration details:

30 ml of a homeopathic syrup was administrated (Drosetux)

Number of subjects in period 1	20 ml balloon + codeine	200 ml balloon + codeine	20 ml balloon + placebo
Started	6	6	6
Completed	6	6	6

Number of subjects in period 1	200 ml balloon + placebo
Started	6
Completed	6

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	6	6	
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)	6	6	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	5	5	
Male	1	1	

End points

End points reporting groups	
Reporting group title	20 ml balloon + codeine
Reporting group description: 20 ml balloon + 60 mg codeine	
Reporting group title	200 ml balloon + codeine
Reporting group description: 200 ml balloon + 60 mg codeine	
Reporting group title	20 ml balloon + placebo
Reporting group description: 20 ml balloon + placebo	
Reporting group title	200 ml balloon + placebo
Reporting group description: 200 ml balloon + placebo	

Primary: gastric contractility (balloon 200ml, codein vs placebo)

End point title	gastric contractility (balloon 200ml, codein vs placebo)[1]

End point description:

Contractility is expressed as motility index (MI)
MI = balloon pressure motility index.
Within the inflated condition, treatment (placebo or codeine) had a significant effect on MI (P<0.01).
Within the deflated condition, treatment did not significantly affect MI.

End point type	Primary

End point timeframe:

comparison of 2 conditions (balloon 200 ml + codeine vs balloon 200 ml + placebo) at timepoint 35 minutes.

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: this is a cross over study with 2 condiditions (balloon 20 ml and balloon 200 ml) and 2 products (codein and plabebo)

End point values	200 ml balloon + codeine	200 ml balloon + placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: Motility Index (MI)				
arithmetic mean (standard deviation)	2.4 (± 1.3)	4.3 (± 1.8)		

Statistical analyses

Statistical analysis title	gastric contractility at timepoint 35 min
Comparison groups	200 ml balloon + codeine v 200 ml balloon + placebo

Number of subjects included in analysis	12
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.01
Method	ANOVA

Primary: gastric contractility (balloon 20 ml, codein vs placebo)

End point title	gastric contractility (balloon 20 ml, codein vs placebo)[2]

End point description:

Contractility is expressed as motility index (MI)
MI = balloon pressure motility index.
Within the inflated condition, treatment (placebo or codeine) had a significant effect on MI (P<0.01).
Within the deflated condition, treatment did not significantly affect MI.

End point type	Primary

End point timeframe:

comparison of 2 conditions (balloon 20 ml + codeine vs balloon 20 ml + placebo) at timepoint 35 minutes.

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: this is a cross over study with 2 condiditions (balloon 20 ml and balloon 200 ml) and 2 products (codein and plabebo)

End point values	20 ml balloon + codeine	20 ml balloon + placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	6		
Units: Motility Index (MI)				
arithmetic mean (standard deviation)	1.7 (± 1.7)	1.4 (± 1.4)		

Statistical analyses

Statistical analysis title	gastric contractility (balloon 20 ml)
Comparison groups	20 ml balloon + placebo v 20 ml balloon + codeine
Number of subjects included in analysis	12
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	ANOVA

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

Dictionary used

Dictionary name	MedDRA
Dictionary version	23

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: Different epigastric symptoms were systematically recorded at various stages during the experiment: bloating, discomfort, nausea and pain. Mild bloating and hunger were often present. These symptoms were not regarded as adverse events.

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