Clinical trial results:
The effect of corticotrophin-releasing hormone (CRH) on esophageal motility in healthy volunteers

Summary

EudraCT number	2014-002239-33
Trial protocol	BE
Global end of trial date	01 December 2014

Results information

Result version number	v1 (current)
This version publication date	04 February 2021
First version publication date	04 February 2021
Summary attachment (see zip file)	Article CRH on esophageal motility (ajpgi.00437.2016.pdf)

Trial information

Trial identification

Sponsor protocol code	CRHMOT2014

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02674256
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 1633 06 71, jan.tack@kuleuven.be
Scientific contact	TARGID, TARGID, KU Leuven, 32 1633 06 71, 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	01 December 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 December 2014
Global end of trial reached?	Yes
Global end of trial date	01 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Determine the effect of CRH-administration on esophageal motility in a group of healthy volunteers

Protection of trial subjects:

The identification of all trial subjects was protected by using subject numbers.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 October 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: 14
Worldwide total number of subjects	14
EEA total number of subjects	14

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)	14
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Healthy volunteers were not allowed to have any gastro-intestinal complaints. The use of medication, except for oral contraceptives, was not allowed for this study.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Post CRH

Arm description:

solution of 100µg CRH powder for injection in 1 mL of NaCL 0.9% was injected intravenous over the course of 1 minute

Arm type	Experimental
Investigational medicinal product name	cortisol releasing hormone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

100µg CRH powder in 1 mL of NaCL 0.9% was injected intravenous over the course of 1 minute

Arm title	Pre CRH

Arm description:

Baseline values

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:

NaCl 0.9%

Number of subjects in period 1	Post CRH	Pre CRH
Started	14	14
Completed	14	14

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	14	14	
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)	14	14	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	26.6		
standard deviation	± 5.8	-	
Gender categorical Units: Subjects			
Female	6	6	
Male	8	8	

End points

End points reporting groups

Reporting group title	Post CRH
Reporting group description:	
solution of 100µg CRH powder for injection in 1 mL of NaCL 0.9% was injected intravenous over the course of 1 minute	
Reporting group title	Pre CRH
Reporting group description:	
Baseline values	

Primary: Distal contractile integral

End point title	Distal contractile integral
End point description:	
End point type	Primary
End point timeframe:	
This endpoint was measured at the same visit. The value of the distal contractile integral pre and post injection of CRH	

End point values	Post CRH	Pre CRH		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	14		
Units: mmHg.s.cm				
median (inter-quartile range (Q1-Q3))	686 (541.3 to 1149)	1391 (926 to 2035)		

Statistical analyses

Statistical analysis title	T test for DCI
Comparison groups	Post CRH v Pre CRH
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.0012
Method	t-test, 2-sided

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

Adverse events were reported from the moment the subjects signed the informed consent until the end of their last study visit.

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: Headache and hunger was reported during this study. This was due to the fact that the volunteers needed to be fasted for the investigation. These adverse events were not related to the adminstration of cortisol releasing hormone.

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