



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 administration 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