# Clinical trial results:
# A placebo controlled trial with Baclofen for the treatment of patients with clinical suspicion of rumination syndrome or esophageal belching

## Summary

| | |
|---|---|
| EudraCT number | 2011-002745-35 |
| Trial protocol | BE |
| Global end of trial date | 30 June 2016 |

**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 baclofen ruminatie (A Randomized Double-Blind, Placebo-Controlled, Cross-Over Study Using Baclofen in the Treatment of Rumination Syndrome.pdf) |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | rum_baclofen2011 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03113396 |
| 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 | 13 April 2017 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 30 June 2016 |
| Global end of trial reached? | Yes |
| Global end of trial date | 30 June 2016 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The Primary objective of this study is to assess the efficacy (assessed by High resolution impedance-manometry recordings and questionnaires) of baclofen (lioresal®) 10mg three times daily vs. placebo in patients with clinical suspicion of rumination or supragastric belching.

Protection of trial subjects:

Subjects identification is protected by using randomisation numbers.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 01 February 2012 |
| 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: 20 |
| Worldwide total number of subjects | 20 |
| EEA total number of subjects | 20 |

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) | 20 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

We included patients attending the outpatient clinic at the University Hospital Gasthuisberg (Leuven, Belgium) with a clinical suspicion of rumination syndrome and/or supra-gastric belching, according to Rome IV criteria

### Pre-assignment

Screening details:

All patients underwent empirical treatment with proton pump inhibitors without full resolution of their symptoms. None of the patients underwent any form of behavioral therapy before inclusion in the study. Exclusion criteria were as follows: >75 years; a history of thoracic or upper abdominal surgery; and prior treatment with baclofen.

### 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** | Baclofen |

Arm description:

Medication consisted of identically looking capsules of baclofen (5 mg) or placebo. Patients were instructed to take one capsule t.i.d. during the fi rst week, which was increased to two capsules (10 mg baclofen) t.i.d. in the second week.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Baclofen |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Medication consisted of identically looking capsules of baclofen (5 mg) or placebo. Patients were instructed to take one capsule t.i.d. during the fi rst week, which was increased to two capsules (10 mg baclofen) t.i.d. in the second week.

| | |
|---|---|
| **Arm title** | Placebo |

Arm description:

Medication consisted of identically looking capsules of baclofen (5 mg) or placebo. Patients were instructed to take one capsule t.i.d. during the fi rst week, which was increased to two capsules (10 mg baclofen) t.i.d. in the second week.

| | |
|---|---|
| Arm type | Placebo |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Tablet |
| Routes of administration | Oral use |

Dosage and administration details:

Medication consisted of identically looking capsules of baclofen (5 mg) or placebo. Patients were instructed to take one capsule t.i.d. during the fi rst week, which was increased to two capsules (10 mg baclofen) t.i.d. in the second week.

| **Number of subjects in period 1** | Baclofen | Placebo |
|---|---|---|
| Started | 20 | 20 |
| Completed | 20 | 20 |

## 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 | 20 | 20 | |
| Age categorical<br>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) | 20 | 20 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age continuous<br>Units: years | | | |
| arithmetic mean | 42 | | |
| full range (min-max) | 18 to 61 | - | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 12 | 12 | |
| Male | 8 | 8 | |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | Baclofen |
| Reporting group description: | |
| Medication consisted of identically looking capsules of baclofen (5 mg) or placebo. Patients were instructed to take one capsule t.i.d. during the fi rst week, which was increased to two capsules (10 mg baclofen) t.i.d. in the second week. | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Medication consisted of identically looking capsules of baclofen (5 mg) or placebo. Patients were instructed to take one capsule t.i.d. during the fi rst week, which was increased to two capsules (10 mg baclofen) t.i.d. in the second week. | |

### Primary: Number of flow events

| | |
|---|---|
| End point title | Number of flow events |
| End point description: | |
| | |
| End point type | Primary |
| End point timeframe: | |
| From signing the informed consent until the end of the last measurement during the second study visit. | |

| End point values | Baclofen | Placebo | | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 20 | 20 | | |
| Units: Number | | | | |
| median (inter-quartile range (Q1-Q3)) | 15 (8 to 45) | 20 (13 to 86) | | |

### Statistical analyses

| Statistical analysis title | Paired t test for flow events |
|---|---|
| Comparison groups | Placebo v Baclofen |
| Number of subjects included in analysis | 40 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | = 0.02 |
| 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 | Patients treated with baclofen |

Reporting group description: -

| Serious adverse events | Patients treated with baclofen | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 20 (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 | Patients treated with baclofen | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 7 / 20 (35.00%) | | |
| Nervous system disorders | | | |
| Sleepiness | | | |
| subjects affected / exposed | 3 / 20 (15.00%) | | |
| occurrences (all) | 3 | | |
| Dizziness | | | |
| subjects affected / exposed | 2 / 20 (10.00%) | | |
| occurrences (all) | 2 | | |
| Acral paresthesia | | | |
| subjects affected / exposed | 2 / 20 (10.00%) | | |
| occurrences (all) | 2 | | |

## 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