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 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 Units: years			
arithmetic mean	42		
full range (min-max)	18 to 61	-	
Gender categorical 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