Clinical trial results:
Reducción de la Ingesta Calórica en la Obesidad Mediante Modulación Farmacológica del Vaciamiento Gástrico

Reduction of Caloric Intake in Obesity through Pharmacological Modulation of Gastric Emptying

Summary

EudraCT number	2004-004066-32
Trial protocol	ES
Global end of trial date	30 December 2010

Results information

Result version number	v1 (current)
This version publication date	06 November 2021
First version publication date	06 November 2021

Trial information

Trial identification

Sponsor protocol code	OB/ERYTH 2004-004066-32

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	VHIR
Sponsor organisation address	Passeig Vall Hebron 119-129, Barcelona, Spain, 08035
Public contact	Joaquin Lopez-Soriano, VHIR, joaquin.lopez.soriano@vhir.org
Scientific contact	Silvia Delgado-Aros, VHIR, delgadoaross@gmail.com

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	30 December 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 December 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Evaluar si la aceleración del vaciamiento gástrico vía farmacológica puede inducir saciedad de forma precoz y, por tanto, reducir la ingesta calórica aguda en sujetos con sobrepeso u obesos sanos.

To evaluate if accelerating gastric emptying through pharmacological means may induce early satiety and thus, diminish caloric intake in overweight or obese healthy subjects

Protection of trial subjects:

Participants were allowed to choose from three different Ensure flavors (chocolate, vanilla and strawberry) and were excluded from enrollment if they expressed a dislike for the taste of the test meal during the consent process.
We used the Hospital Anxiety and Depressions Scale to measure depression and anxiety scores.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2006
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	Spain: 30
Worldwide total number of subjects	30
EEA total number of subjects	30

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)	30
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

We included overweight and obese (BMI>25Kgm-2) healthy subjects from the community, who were 18–65 years of age, with no gastrointestinal disease or symptoms.

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?	Yes
Arm title	Erythomycin

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Erythromycin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

60min infusion of intravenous erythromycin (3mg/Kg)

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Saline 0.9%
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

60min infusion of intravenous saline

Number of subjects in period 1	Erythomycin	Placebo
Started	15	15
Completed	15	15

Baseline characteristics

Reporting groups	
Reporting group title	Erythomycin
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Erythomycin	Placebo	Total
Number of subjects	15	15	30
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	37	36	
full range (min-max)	32 to 42	31 to 41	-
Gender categorical Units: Subjects			
Female	12	12	24
Male	3	3	6

End points

End points reporting groups

Reporting group title	Erythomycin
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Acceleration gastric emptying

End point title	Acceleration gastric emptying
End point description:	
Participants drank a nutrient liquid meal (Ensure Plus: 105Kcalml-1, 11% fat, 73% carbohydrate and 16% protein) at a constant rate (30mlmin-1.). Every 5min, participants scored their perception of fullness using a sixgrade scale that combines verbal descriptors and numbers (0=no sensation, 5=maximum fullness, I cannot eat more). Participants were asked to stop meal intake when they reached the score of 5.	
End point type	Primary
End point timeframe:	
3o min after finishing drink test	

End point values	Erythomycin	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: percent				
arithmetic mean (standard deviation)	11.0 (± 2.8)	-1.2 (± 2.7)		

Statistical analyses

Statistical analysis title	Gastric emptying
Comparison groups	Placebo v Erythomycin
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.001
Method	ANOVA

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: All the study (2 days)	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	14.1

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: No serious events were reported. Design of trial did not llow to collect other adverse effects

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The effects of plasma hormones were not primary end points of the study. Administration of a prokinetic drug before meals might help to prevent weight gain, but currently there is unavailability of suitable agents

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/20938444