



Clinical trial results:

The role of induced phase 3 contractions in the control of hunger and food intake

Summary

EudraCT number	2011-004082-33
Trial protocol	BE
Global end of trial date	25 August 2014

Results information

Result version number	v1 (current)
This version publication date	04 February 2021
First version publication date	04 February 2021

Trial information

Trial identification

Sponsor protocol code	erythstom2
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02633579
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	UZLeuven
Sponsor organisation address	herestraat 49, leuven, Belgium, 3000
Public contact	Jan Tack, UZLeuven, 00 3216330147, jan.tack@med.kuleuven.be
Scientific contact	Jan Tack, UZLeuven, 00 3216330147, jan.tack@med.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	20 January 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 August 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Investigating if contractions are necessary to induce hunger feelings, or if erythromycin has a secondary effect

Protection of trial subjects:

only healthy volunteers could participate

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 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: 15
Worldwide total number of subjects	15
EEA total number of subjects	15

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)	15
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

15 healthy volunteers

Pre-assignment

Screening details:

Volunteers were eligible to participate if they were healthy, aged between 18 and 60 y, had a BMI (in kg/m²) between 18 and 25, Exclusion criteria were gastrointestinal diseases, abdominal surgery (appendectomy allowed), psychiatric illnesses, and usage of drugs affecting the GIT. Not allergic to macrolide antibiotics

Period 1

Period 1 title	overall trial period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	No
Arm title	erythromycin 40 mg infusion

Arm description:

at fixed time points (90, 180, and 270 min) an intravenous infusion of placebo or 40 mg erythromycin was administered over a 20-min period in a volume of 100 mL 0.9% NaCl. Administration was done in a single-blind randomized fashion. Each subject received 3 infusions during the measuring period, 2 of which were saline and 1 of which was an infusion of erythromycin

Arm type	Experimental
Investigational medicinal product name	erythromycin 40 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

an intravenous infusion of 40 mg erythromycin was administered over a 20-min period in a volume of 100 mL 0.9% NaCl

Arm title	placebo 0.9% NaCl infusion
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Arm description:

at fixed time points (90, 180, and 270 min) an intravenous infusion of placebo or 40 mg erythromycin was administered over a 20-min period in a volume of 100 mL 0.9% NaCl. Administration was done in a single-blind randomized fashion. Each subject received 3 infusions during the measuring period, 2 of which were saline and 1 of which was an infusion of erythromycin.

Arm type	Placebo
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Investigational medicinal product name	0.9% NaCl
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

an intravenous infusion of 100 mL 0.9% NaCl (= placebo)
was administered over a 20-min period

Number of subjects in period 1	erythromycin 40 mg infusion	placebo 0.9% NaCl infusion
Started	15	15
Completed	15	15

Baseline characteristics

Reporting groups

Reporting group title	overall trial period
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Reporting group description: -

Reporting group values	overall trial period	Total	
Number of subjects	15	15	
Age categorical			
healthy volunteers			
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)	15	15	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
healthy volunteers			
Units: years			
arithmetic mean	28		
standard deviation	± 3	-	
Gender categorical			
Units: Subjects			
Female	9	9	
Male	6	6	

End points

End points reporting groups

Reporting group title	erythromycin 40 mg infusion
Reporting group description: at fixed time points (90, 180, and 270 min) an intravenous infusion of placebo or 40 mg erythromycin was administered over a 20-min period in a volume of 100 mL 0.9% NaCl. Administration was done in a single-blind randomized fashion. Each subject received 3 infusions during the measuring period, 2 of which were saline and 1 of which was an infusion of erythromycin	
Reporting group title	placebo 0.9% NaCl infusion
Reporting group description: at fixed time points (90, 180, and 270 min) an intravenous infusion of placebo or 40 mg erythromycin was administered over a 20-min period in a volume of 100 mL 0.9% NaCl. Administration was done in a single-blind randomized fashion. Each subject received 3 infusions during the measuring period, 2 of which were saline and 1 of which was an infusion of erythromycin.	

Primary: increase of food intake

End point title	increase of food intake
End point description:	
End point type	Primary
End point timeframe: In comparison with placebo, administration of erythromycin significantly (Wilcoxon's signed rank test, $P = 0.015$) increased food intake, with 53% \pm 13% of erythromycin infusions inducing food intake compared with 10% \pm 5% for placebo administration	

End point values	erythromycin 40 mg infusion	placebo 0.9% NaCl infusion		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	15	15		
Units: percentage				
arithmetic mean (standard deviation)	53 (\pm 13)	10 (\pm 5)		

Statistical analyses

Statistical analysis title	food intake
Comparison groups	erythromycin 40 mg infusion v placebo 0.9% NaCl infusion

Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	superiority ^[1]
P-value	= 0.015
Method	Wilcoxon (Mann-Whitney)

Notes:

[1] - erythromycin versus placebo. This is a cross over study. All 15 subjects participated in both study arms

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

For each individual, corresponds to timeframe of study participation (from signing of informed consent until last visit).

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	0
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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 adverse events were reported

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/26817505>