Clinical trial results:
The effect of acotiamide on gastric motility and satiation in healthy volunteers

Summary

EudraCT number	2014-002092-28
Trial protocol	BE
Global end of trial date	27 July 2017

Results information

Result version number	v1 (current)
This version publication date	26 February 2021
First version publication date	26 February 2021

Trial information

Trial identification

Sponsor protocol code	acotiamide1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZLeuven / KULeuven / TARGID
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3000
Public contact	Jan Tack, KULeuven , 0032 16344225, jan.tack@kuleuven.be
Scientific contact	TARGID, KULeuven , 0032 16377535, florencia.carbone@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	29 January 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 July 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this trial is to investigate the effect of acotiamide in gastric accommodation and satiation during and after meal

Protection of trial subjects:

healthy volunteers

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 April 2017
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:

Healthy subjects aged between 18 and 60 years

Pre-assignment

Screening details:

At inclusion, subjects did not show any gastrointestinal symptoms and were not taking any medication known to influence gastrointestinal sensorimotor function.

Period 1

Period 1 title	overal study 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	acotiamide

Arm description:

acotiamide 100 mg, three times daily

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

Dosage and administration details:

acotiamide 100 mg, three times daily, taken orally.

Arm title	placebo

Arm description: -

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:

placebo tablet, three times daily, taken orally.

Number of subjects in period 1	acotiamide	placebo
Started	20	20
Completed	20	20

Baseline characteristics

Reporting groups	
Reporting group title	overal study period
Reporting group description: cross over study design	

Reporting group values	overal study 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	27		
standard deviation	± 7	-	
Gender categorical Units: Subjects			
Female	10	10	
Male	10	10	

End points

End points reporting groups

Reporting group title	acotiamide
Reporting group description: acotiamide 100 mg, three times daily	
Reporting group title	placebo
Reporting group description: -	

Primary: gastric emptying rate

End point title	gastric emptying rate
End point description: subjects consumed a standardized solid meal consisting of one scrambled egg (of which the yolk was labeled with 100 mg nonradioactive (13C)octanoic acid), two slices of white bread and 150 mL of water within 10 minutes. Breath samples were collected before administration of the study drug (in duplo), and every 15 minutes after the ingestion of the nonradioactive (13C)octanoic acid for 4 hours by exhaling in an exetainer.	
End point type	Primary
End point timeframe: Gastric emptying rate was assessed by a 13Coctanoic acid breath test after 3 weeks treatment with acotiamide or placebo (cross over study design)	

End point values	acotiamide	placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20[1]	20[2]		
Units: minute				
arithmetic mean (standard deviation)	7.33 (± 24.7)	59.7 (± 35.6)		

Notes:

[1] - cross over study

[2] - cross over study

Statistical analyses

Statistical analysis title	gastric emptying rate
Comparison groups	placebo v acotiamide
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.92 [3]
Method	Mixed models analysis

Notes:

[3] - There was no difference in GE half time between both treatments (P = 0.92).

Adverse events

Adverse events information

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

Dictionary used

Dictionary name	MedDRA
Dictionary version	23

Reporting groups

Reporting group title	during acotiamide treatment
Reporting group description: -	
Reporting group title	during placebo treatment

Reporting group description: -

Serious adverse events	during acotiamide treatment	during placebo treatment	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)	0 / 20 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	during acotiamide treatment	during placebo treatment	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 20 (10.00%)	4 / 20 (20.00%)	
General disorders and administration site conditions			
headache			
subjects affected / exposed	2 / 20 (10.00%)	2 / 20 (10.00%)	
occurrences (all)	2	2	
cold			
subjects affected / exposed	0 / 20 (0.00%)	2 / 20 (10.00%)	
occurrences (all)	0	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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30663175