Clinical trial results:
The effect of mirtazapine (REMERGON®) on gastric motility and satiation in healthy subjects

Summary

EudraCT number	2014-004862-89
Trial protocol	BE
Global end of trial date	23 February 2016

Results information

Result version number	v1 (current)
This version publication date	14 February 2021
First version publication date	14 February 2021

Trial information

Trial identification

Sponsor protocol code	mirtazapine1

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, UZLeuven / KULeuven / TARGID, 0032 16344225, jan.tack@kuleuven.be
Scientific contact	Florencia Carbone, UZLeuven / KULeuven / TARGID, 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	22 November 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 February 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of the study is to investigate the mechanism of work of mitrazipine (Remergon) in gastric motility and sensivity, and satiation in healthy volunteers.

Protection of trial subjects:

not applicable

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 February 2015
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: 31
Worldwide total number of subjects	31
EEA total number of subjects	31

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)	31
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Healthy volunteers had to be devoid of GI symptoms and of the use of medications known to influence gastrointestinal sensorimotor function.

Pre-assignment

Screening details:

Healthy volunteers, recruited by public advertisement

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?	Yes
Arm title	mirtazapine

Arm description: -

Arm type	Experimental
Investigational medicinal product name	mirtazapine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Orodispersible tablet
Routes of administration	Oral use

Dosage and administration details:

Treatment consisted of a 3-week dosing of mirtazapine (15 mg) every night before sleeping for 3 weeks

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:

Treatment consisted of a 3-week dosing of 1 placebo tablet every night before sleeping for 3 weeks

Number of subjects in period 1	mirtazapine	placebo
Started	16	15
Completed	14	14
Not completed	2	1
Adverse event, non-fatal	1	-

intolerance of barostat procedure	1	1

Baseline characteristics

Reporting groups	
Reporting group title	mirtazapine
Reporting group description: -	
Reporting group title	placebo
Reporting group description: -	

Reporting group values	mirtazapine	placebo	Total
Number of subjects	16	15	31
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	16	15	31
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	23.9	24.9	
standard deviation	± 1.3	± 1.0	-
Gender categorical Units: Subjects			
Female	9	9	18
Male	7	6	13

End points

End points reporting groups

Reporting group title	mirtazapine
Reporting group description: -	
Reporting group title	placebo
Reporting group description: -	

Primary: The effect of mirtazapine on intragastric volume after a meal

End point title	The effect of mirtazapine on intragastric volume after a meal
End point description:	
End point type	Primary
End point timeframe:	
the effect of mirtazapine/placebo on gastric accommodation was measured with gastric barostat measurement at the end of a 3 week treatment with mirtazapine / placebo	

End point values	mirtazapine	placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	14	14		
Units: ml				
arithmetic mean (standard deviation)	216.23 (± 29.25)	297.17 (± 40.65)		

Statistical analyses

Statistical analysis title	gastric accommodation after 3 week treatment
Statistical analysis description:	
At baseline, the meal-induced increase in intragastric balloon volume (accommodation) was similar in both treatment groups (placebo: 271.49±42.67 mL and mirtazapine: 206.08±50.5 mL, P=.24). No differences were observed after 3 weeks of treatment with placebo (297.17±40.65 mL; P=.69). After 3 weeks of treatment with mirtazapine, the intragastric barostat balloon volume was not significantly altered (216.23±29.25 mL; P=.85).	
Comparison groups	mirtazapine v placebo
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05 [1]
Method	t-test, 2-sided

Notes:

[1] - In all analyses, P <.05 was considered statistically significant.
No significant differences were found in the gastric accommodation.

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	mirtazapine arm
Reporting group description: -	
Reporting group title	placebo group

Reporting group description: -

Serious adverse events	mirtazapine arm	placebo group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 16 (0.00%)	0 / 15 (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	mirtazapine arm	placebo group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 16 (62.50%)	6 / 15 (40.00%)	
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 16 (25.00%)	3 / 15 (20.00%)	
occurrences (all)	4	3	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	8 / 16 (50.00%)	2 / 15 (13.33%)	
occurrences (all)	8	2	
Dizziness			
subjects affected / exposed	1 / 16 (6.25%)	0 / 15 (0.00%)	
occurrences (all)	1	0	

Gastrointestinal disorders Gastroenteritis subjects affected / exposed occurrences (all)	 2 / 16 (12.50%) 2	 2 / 15 (13.33%) 2	
Skin and subcutaneous tissue disorders Skin reaction subjects affected / exposed occurrences (all)	 Additional description: urticarial rash 1 / 16 (6.25%) 1	 0 / 15 (0.00%) 0	

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/28695632