Clinical trial results:
SOMATULINE Autogel 90 mg IN DUMPING SYNDROME

Summary

EudraCT number	2008-000643-34
Trial protocol	BE
Global end of trial date	15 November 2013

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	Som-001

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZLeuven
Sponsor organisation address	herestraat 49, Leuven, Belgium, 3000
Public contact	lieselot Holvoet, uzleuven, lieselot.holvoet@uzleuven.be
Scientific contact	jan tack, uzleuven, jan.tack@uzleuven.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	11 February 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	15 November 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of Somatuline 90 mg versus placebo in the treatment of dumping syndrome by using a specific Treatment Assessment Scale and a specific dumping score.

Protection of trial subjects:
nothing in particular
Background therapy: -
Evidence for comparator: -

Actual start date of recruitment	18 July 2008
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: 24
Worldwide total number of subjects	24
EEA total number of subjects	24

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)	22
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

patients fulfilling inclusion/exclusion criteria were recruited

Pre-assignment

Screening details:

In total, 33 patients were assessed for eligibility, with nine screening failures (three with gallstones, three previous exposure to OCT, one diabetes mellitus, one pregnancy and one with DS <10), resulting in 24 patients included and randomised in the trial (12 to LAN and 12 placebo first;

Period 1

Period 1 title	overall period (cross over trial)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	treatment order LAN - placebo

Arm description:

patient started with active treatment = lanreotide during first treatment period.
Before cross over pt was treated with active treatment (=LAN). After wash out (5 weeks) and cross over, pt was treated with placebo

Arm type	Experimental
Investigational medicinal product name	lanreotide autogel 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

prefilled syringe. Deep SC every 4 weeks during 3 months = 3 injections/treatment period. deep SC injection.

Investigational medicinal product name	placebo (NaCl 0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

prefilled syringe. Deep SC every 4 weeks during 3 months = 3 injections/treatment period.

Arm title	treatment order placebo -LAN

Arm description:

patient started with placebo treatment = placebo during first treatment period.
Before cross over pt was treated with placebo. After wash out (5 weeks) and cross over, pt was treated with active treatment (=LAN)

Arm type	Experimental

Investigational medicinal product name	lanreotide autogel 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Prefilled syringe. Deep SC every 4 weeks during 3 months = 3 injections/treatment period. deep SC injection.

Investigational medicinal product name	placebo (NaCl 0.9%)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

prefilled syringe. Deep SC every 4 weeks during 3 months = 3 injections/treatment period.

Number of subjects in period 1	treatment order LAN - placebo	treatment order placebo -LAN
Started	12	12
wash out period	9	12
Completed	8	9
Not completed	4	3
Adverse event, serious fatal	2	-
Consent withdrawn by subject	1	1
Adverse event, non-fatal	1	2

Baseline characteristics

Reporting groups

Reporting group title	treatment order LAN - placebo

Reporting group description:

patient started with active treatment = lanreotide during first treatment period.
Before cross over pt was treated with active treatment (=LAN). After wash out (5 weeks) and cross over, pt was treated with placebo

Reporting group title	treatment order placebo -LAN

Reporting group description:

patient started with placebo treatment = placebo during first treatment period.
Before cross over pt was treated with placebo. After wash out (5 weeks) and cross over, pt was treated with active treatment (=LAN)

Reporting group values	treatment order LAN - placebo	treatment order placebo -LAN	Total
Number of subjects	12	12	24
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	48	47	
inter-quartile range (Q1-Q3)	45 to 52	36 to 59	-
Gender categorical Units: Subjects			
Female	6	10	16
Male	6	2	8

End points

End points reporting groups

Reporting group title	treatment order LAN - placebo

Reporting group description:

patient started with active treatment = lanreotide during first treatment period.
Before cross over pt was treated with active treatment (=LAN). After wash out (5 weeks) and cross over, pt was treated with placebo

Reporting group title	treatment order placebo -LAN

Reporting group description:

patient started with placebo treatment = placebo during first treatment period.
Before cross over pt was treated with placebo. After wash out (5 weeks) and cross over, pt was treated with active treatment (=LAN)

Primary: dumping score

End point title	dumping score

End point description:

Total DS is calculated as the sum of eight early and six late dumping symptoms, as described by Arts et al. (Clin Gastroenterol Hepatol 2009; 7: 432–437).Early dumping symptoms include sweating, flushes, dizziness, palpitations, abdominal pain, diarrhoea, bloating and nausea occurring within one hour after a meal. Late dumping symptoms include sweating, palpitations, hunger, drowsiness
to unconsciousness, shaking and aggression occurring an hour or more after a meal. Symptoms were cored using a four-point Likert scale (0 none, 1 mild, 2 moderate or 3 severe). Pooled total DS before (week 0) and after (week 11) each treatment were compared within and between groups.

End point type	Primary

End point timeframe:

week 11 after start of randomized treatment

End point values	treatment order LAN - placebo	treatment order placebo - LAN		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8[1]	9[2]		
Units: symptom score				
number (not applicable)	8	9		

Notes:

[1] - Cross-over trial; for subject number details: see publication

[2] - see comment for group 1

Statistical analyses

Statistical analysis title	Dumping score after 11 weeks

Statistical analysis description:

Dumping severity score, sum of individual symptoms, compared after 11 weeks in each treatment group

Comparison groups	treatment order LAN - placebo v treatment order placebo -LAN

Number of subjects included in analysis	17
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.21 [4]
Method	Wilcoxon (Mann-Whitney)

Notes:

[3] - LAN versus placebo. This is a cross-over trial. All patients received both study treatments

[4] - between-group comparison not significant at this sample size.

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	0

Reporting groups

Reporting group title	LAN treatment
Reporting group description: -	
Reporting group title	placebo treatment

Reporting group description: -

Serious adverse events	LAN treatment	placebo treatment	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 24 (8.33%)	0 / 21 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Nervous system disorders			
epilepsia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
hypoglycemia			
subjects affected / exposed	1 / 24 (4.17%)	0 / 21 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	LAN treatment	placebo treatment	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 24 (91.67%)	16 / 21 (76.19%)	
Gastrointestinal disorders			

Diarrhoea subjects affected / exposed occurrences (all)	12 / 24 (50.00%) 12	6 / 21 (28.57%) 6	
Endocrine disorders hypoglycemia subjects affected / exposed occurrences (all)	5 / 24 (20.83%) 5	5 / 21 (23.81%) 5	
Infections and infestations Infection subjects affected / exposed occurrences (all)	5 / 24 (20.83%) 5	9 / 21 (42.86%) 9	

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/31662863