Clinical trial results:
Pilot Study with Treatment of Short Bowel Syndrome Patients with end-jejunostomi with the Glucagon-Like Peptide-1 analogue, Liraglutide (Victoza®)

Summary

EudraCT number	2013-005499-16
Trial protocol	DK
Global end of trial date	20 June 2014

Results information

Result version number	v1 (current)
This version publication date	26 June 2022
First version publication date	26 June 2022
Summary attachment (see zip file)	manuscript (Hvistendahl2016.pdf) supplementary material (Supplementary_Materials_online_supp.pdf)

Trial information

Trial identification

Sponsor protocol code	2013-624

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Rigshospitalet
Sponsor organisation address	Inge Lehmanns Vej 7, Copenhagen, Denmark, 2100
Public contact	Palle Bekker Jeppesen, Department of Intestinal Failure and LIver Diseases, clinic 2101, +45 20481323, bekker@dadlnet.dk
Scientific contact	Palle Bekker Jeppesen, Department of Intestinal Failure and LIver Diseases, clinic 2101, +45 20481323, bekker@dadlnet.dk

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	02 October 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 June 2014
Global end of trial reached?	Yes
Global end of trial date	20 June 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the trial is to assessthe therapeutic effect of the glucagon-like peptide-1 analogue, liraglutide (Victoza®) for SBS patients with an end-jejunostomi. The efficacy is assessed through the ability of liraglutide (Victoza®) to increase intestinal absorption, reduce diarrhea and the need for hyperphagia, and determine if liraglutide (Victoza®) can reduce the need for parenteral support.

Protection of trial subjects:

Several safety parameters were done during the trial period, including a physical examination, electrocardiography, vital signs, local tolerability and blood samples.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	03 February 2014
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	Denmark: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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)	3
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Dates of recruitment: from 3rd February 2014 to 17th March 2014.
Recruitment was done through the out-patient clinic database at Department of Intestinal Failure and Liver Diseases, clinic 2101, Inge Lehmanns Vej 7, DK-2100 Copenhagen, Denmark

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	8
Number of subjects completed	8

Period 1

Period 1 title	Change after 8 weeks treatment
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

NA

Arms

Arm title	8 weeks on liraglutide treatment

Arm description:

All endpoints and explorative assessments done at the first baseline balance study were repeated at this period "8 weeks on liraglutide treatment". All outcome data were compared with baseline values.

Arm type	Active comparator
Investigational medicinal product name	Liraglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Uptitration to 1.8 mg/day, subcutanous injections

Number of subjects in period 1	8 weeks on liraglutide treatment
Started	8
Completed	8

Period 2

Period 2 title	Baseline
Is this the baseline period?	Yes[1]
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	8 weeks on liraglutide treatment

Arm description:

All endpoints and explorative assessments done at the first baseline balance study were repeated at this period "8 weeks on liraglutide treatment". All outcome data were compared with baseline values.

Arm type	Active comparator
Investigational medicinal product name	Liraglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Uptitration to 1.8 mg/day, subcutanous injections

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Period 1 is the baseline period

Number of subjects in period 2	8 weeks on liraglutide treatment
Started	8
Completed	8

Baseline characteristics

Reporting groups	
Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	8	8	
Age categorical Units: Subjects			
Adults (18-64 years)	3	3	
From 65-84 years	5	5	
Age continuous			
Age			
Units: years arithmetic mean standard deviation	63 ± 11	-	
Gender categorical Units: Subjects			
Female	3	3	
Male	5	5	
Wet weight dietary intake			
Measured by 72-hour metabolic balance study			
Units: kg/day arithmetic mean standard deviation	2.7 ± 0.8	-	
Wet Weight Ostomy Output			
Measured from 72-hour metabolic balance study			
Units: kg/day arithmetic mean standard deviation	3.2 ± 1.4	-	
Parenteral support volume			
Measured from 72-hour metabolic balance study			
Units: L/day arithmetic mean standard deviation	3.3 ± 2.2	-	
Energy dietary intake			
Measured from 72-hour metabolic balance study			
Units: kJ/day arithmetic mean standard deviation	10147 ± 2584	-	
Energy ostomy output			
Measured from 72-hour metabolic balance study			
Units: kJ/day arithmetic mean standard deviation	6904 ± 3390	-	
Energy parenteral intake Units: kJ/day arithmetic mean	4375		

standard deviation	± 2936	-	
Urine output			
Measured from 72-hour metabolic balance study			
Units: L/day			
arithmetic mean	1543		
standard deviation	± 532	-	

End points

End points reporting groups

Reporting group title	8 weeks on liraglutide treatment
Reporting group description:	
All endpoints and explorative assessments done at the first baseline balance study were repeated at this period "8 weeks on liraglutide treatment". All outcome data were compared with baseline values.	
Reporting group title	8 weeks on liraglutide treatment
Reporting group description:	
All endpoints and explorative assessments done at the first baseline balance study were repeated at this period "8 weeks on liraglutide treatment". All outcome data were compared with baseline values.	

Primary: Change in wet weight ostomy output

End point title	Change in wet weight ostomy output[1]
End point description:	
End point type	Primary
End point timeframe:	
After 8 weeks of treament	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: system wont allow posting

End point values	8 weeks on liraglutide treatment			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: g/day				
arithmetic mean (standard deviation)	-474 (± 563)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in wet weight dietary intake

End point title	Change in wet weight dietary intake
End point description:	
End point type	Secondary
End point timeframe:	
After 8 weeks of treatment	

End point values	8 weeks on liraglutide treatment			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: g/day				
arithmetic mean (standard deviation)	9 (± 57)			

Statistical analyses

No statistical analyses for this end point

Secondary: Urine volume

End point title	Urine volume

End point description:

End point type	Secondary

End point timeframe:

Change from baseline after 8 weeks of treament

End point values	8 weeks on liraglutide treatment			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: g/day				
arithmetic mean (standard deviation)	765 (± 759)			

Statistical analyses

No statistical analyses for this end point

Secondary: Wet weight absorption

End point title	Wet weight absorption

End point description:

End point type	Secondary

End point timeframe:

Change from baseline after 8 weeks of treatment

End point values	8 weeks on liraglutide treatment			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: g/day				
arithmetic mean (standard deviation)	464 (± 557)			

Statistical analyses

No statistical analyses for this end point

Secondary: Instestinal energy absorption

End point title	Instestinal energy absorption

End point description:

End point type	Secondary

End point timeframe:

Change from baseline after 8 weeks of treatment

End point values	8 weeks on liraglutide treatment			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: kJ/day				
arithmetic mean (standard deviation)	902 (± 882)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

8 weeks treatment

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	1

Reporting groups

Reporting group title	After 8 weeks of treatment

Reporting group description: -

Serious adverse events	After 8 weeks of treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	After 8 weeks of treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)		

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: system wont allow posting

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