Clinical trial results:
Treatment of bile acid malabsorption with liraglutid

Summary

EudraCT number	2018-003575-34
Trial protocol	DK
Global end of trial date	01 February 2021

Results information

Result version number	v1 (current)
This version publication date	09 September 2022
First version publication date	09 September 2022

Trial information

Trial identification

Sponsor protocol code	301084

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Herlev og Gentofte Hospital
Sponsor organisation address	Gentofte Hospitalsvej 7, Hellerup, Denmark, 2900
Public contact	Stene Diabetes Center Copenhagen,, Gentofte Hospital, University of Copenhagen, martin.lund.kaarhus@regionh.dk
Scientific contact	Stene Diabetes Center Copenhagen,, Gentofte Hospital, University of Copenhagen, 0045 38674266, martin.lund.kaarhus@regionh.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	06 May 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 January 2021
Global end of trial reached?	Yes
Global end of trial date	01 February 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The aim of this study is to examine the influence of liraglutide on individuals suffering from bile acid malabsorption (BAM), in a randomised double-blinded, double dummy parallel Group non-inferiority study.

Protection of trial subjects:	
Visits at the experimental site	
Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	09 January 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Denmark: 52
Worldwide total number of subjects	52
EEA total number of subjects	52

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)	45
From 65 to 84 years	7
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

diagnosed Subjects were asked if a MD was allowed to contact them for further information about the study

Pre-assignment

Screening details:

Lægelig vurdering samt opfyldelse af inklusionskriterier

Pre-assignment period milestones

Number of subjects started	52
Number of subjects completed	52

Period 1

Period 1 title	baseline
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	baseline
Arm description: -	
Arm type	baseline
Investigational medicinal product name	none
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Not assigned
Routes of administration	Not mentioned

Dosage and administration details:

0

Number of subjects in period 1	baseline
Started	52
Completed	52

Period 2	
Period 2 title	intervention
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms	
Are arms mutually exclusive?	Yes
Arm title	Liraglutide
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	liraglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for dispersion for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 0.6 to 1.8 mg	
Arm title	Colesevelam
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	colesevelam
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, soft + tablet
Routes of administration	Oral use
Dosage and administration details: 1.875 g twice daily	

Number of subjects in period 2	Liraglutide	Colesevelam
Started	26	26
Completed	25	25
Not completed	1	1
Adverse event, non-fatal	1	1

Baseline characteristics

Reporting groups	
Reporting group title	baseline

Reporting group description: -

Reporting group values	baseline	Total	
Number of subjects	52	52	
Age categorical Units: Subjects			
Adults (18-64 years)	45	45	
From 65-84 years	7	7	
Age continuous Units: years			
arithmetic mean	51.7		
standard deviation	± 13.3	-	
Gender categorical Units: Subjects			
Female	33	33	
Male	19	19	

End points

End points reporting groups	
Reporting group title	baseline
Reporting group description: -	
Reporting group title	Liraglutide
Reporting group description: -	
Reporting group title	Colesevelam
Reporting group description: -	

Primary: Risk difference between interventions	
End point title	Risk difference between interventions
End point description:	
End point type	Primary
End point timeframe:	
6 weeks of intervention	

End point values	Liraglutide	Colesevelam		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	26		
Units: %	56	23		

Statistical analyses

Statistical analysis title	Risk difference
Comparison groups	Liraglutide v Colesevelam
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	non-inferiority
Parameter estimate	Risk difference (RD)
Point estimate	0
Confidence interval	
level	95 %
sides	1-sided
lower limit	-1

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From intervention start and three weeks after last intervention	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	no specific
Dictionary version	1

Reporting groups	
Reporting group title	Liraglutide
Reporting group description: -	
Reporting group title	Colesevelam
Reporting group description: -	

Serious adverse events	Liraglutide	Colesevelam	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 26 (0.00%)	0 / 26 (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	Liraglutide	Colesevelam	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 26 (23.08%)	1 / 26 (3.85%)	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	6 / 26 (23.08%)	1 / 26 (3.85%)	
occurrences (all)	26	26	

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? Yes

Date	Interruption	Restart date
16 March 2020	SARSCOV2 virus paused the project for 4 months	-

Notes:

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/35868334