Clinical trial results:
Effects of GLP-1 receptor agonist treatment on pulmonary function and quality of life in obese patients with chronic obstructive pulmonary disease -
A prospective, randomized, placebo-controlled, double-blinded, parallel group, two-center trial for the evaluation of the effect of Liraglutide 3 mg daily on chronic obstructive pulmonary disease.

Summary

EudraCT number	2017-003551-32
Trial protocol	DK
Global end of trial date	19 March 2020

Results information

Result version number	v1 (current)
This version publication date	24 January 2025
First version publication date	24 January 2025
Summary attachment (see zip file)	Abstract (Abstract.docx) Respiratory Effects of Treatment with a Glucagon-Like Peptide-1 Receptor Agonist in Patients Suffering from Obesity and Chronic Obstructive Pulmonary Disease (copd-17-405.pdf) FDG-PET/CT-based respiration-gated lung segmentation and quantification of lung inflammation in COPD patients (13104_2024_Article_6820.pdf)

Trial information

Trial identification

Sponsor protocol code	ISS-U1111-1188-8695

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03466021
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Hospital of South West Jutland
Sponsor organisation address	Finsensgade 35, Esbjerg, Denmark, 6700
Public contact	Medical Department, Hospital of South West Jutland, 45 60867172, claus.bogh.juhl@rsyd.dk
Scientific contact	Medical Department, Hospital of South West Jutland, 45 60867172, claus.bogh.juhl@rsyd.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	01 July 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 March 2020
Global end of trial reached?	Yes
Global end of trial date	19 March 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of the study is to evaluated the effect of Liraglutide 3mg on patient reported outcomes and objective measures of COPD

Protection of trial subjects:

Patients were regularly seen by a medical doctor, patients were informed about normal and abnormal findings throughout the trial

Background therapy:

Usual medication for chronic obstructive pulmonary disease. Systemic steroid permitted for intermittent use.

Evidence for comparator:

Inhaled steroids, beta-2 agonists and anticholinergic agents are all well documentet treatments of chrinoc obstructive pulmonary disease.

Actual start date of recruitment	15 January 2018
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: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	14
From 65 to 84 years	26
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited from the outpatient clinics for people with chronic obstructive pulmonary disease and from newspaper advertisements

Pre-assignment

Screening details:

Presence of chronic obstructive pulkmonary disease and BMI > 27kg/m2

Pre-assignment period milestones

Number of subjects started	40
Number of subjects completed	40

Period 1

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

Blinding implementation details:

Use of matching placebo, unblinded after database-lock

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Matching placebo

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	NA
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Abdominal injection

Arm title	Liraglutide

Arm description:

Liraglutide

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

Dosage and administration details:

Gradually increasing does starting with 0.6 mg daily, weekly uptitratetd to full dosis of 3.0 mg daily

Number of subjects in period 1	Placebo	Liraglutide
Started	20	20
Completed	20	19
Not completed	0	1
Physician decision	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description: Matching placebo	
Reporting group title	Liraglutide
Reporting group description: Liraglutide	

Reporting group values	Placebo	Liraglutide	Total
Number of subjects	20	20	40
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)	20	20	40
From 65-84 years	0	0	0
85 years and over	0	0	0
18-64	0	0	0
Age continuous Units: years			
arithmetic mean	65.2	66.6	
standard deviation	± 8.5	± 6.8	-
Gender categorical Units: Subjects			
Female	9	7	16
Male	11	13	24
FVC			
functional vital capacity baseline			
Units: Liter			
arithmetic mean	2.83	3.16	
standard deviation	± 0.99	± 1.01	-
Bodyweight Units: kilogram(s)			
arithmetic mean	102.5	104.4	
standard deviation	± 18.0	± 13.6	-

End points

End points reporting groups	
Reporting group title	Placebo
Reporting group description: Matching placebo	
Reporting group title	Liraglutide
Reporting group description: Liraglutide	

Primary: FVC	
End point title	FVC
End point description: Functional vital capacity, lung capacity, week 40	
End point type	Primary
End point timeframe: Week 40	

End point values	Placebo	Liraglutide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	19		
Units: litre(s)				
arithmetic mean (standard deviation)	2.83 (± 0.96)	3.16 (± 0.98)		

Statistical analyses

Statistical analysis title	Effect analysis
Statistical analysis description: Effect of liraglutide compared to placebo Intention to treat analysis	
Comparison groups	Placebo v Liraglutide
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Random effect model

Secondary: Body weight	
End point title	Body weight

End point description:

End point type	Secondary

End point timeframe:

baseline to week 40

End point values	Placebo	Liraglutide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	19		
Units: kilogram(s)				
arithmetic mean (standard deviation)	105.9 (± 18.1)	98.2 (± 13.3)		

Statistical analyses

Statistical analysis title	Effect analysis

Statistical analysis description:

Compares the effecct of liraglutide with the effect of placebo
Intention to treat analysis

Comparison groups	Placebo v Liraglutide
Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Random effect model
Parameter estimate	Random effect model

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 0-40 weeks	
Adverse event reporting additional description: Gastrointestinal side effects	
Assessment type	Systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	5.0

Reporting groups	
Reporting group title	Arm Liraglutide
Reporting group description: -	
Reporting group title	Arm Placebo
Reporting group description: -	

Serious adverse events	Arm Liraglutide	Arm Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 19 (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: 0.05 %

Non-serious adverse events	Arm Liraglutide	Arm Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 19 (15.79%)	0 / 20 (0.00%)	
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	3 / 19 (15.79%)	0 / 20 (0.00%)	
occurrences (all)	3	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