



Clinical trial results:

The effectiveness of pharmacological treatment with the glucagon-like peptide-1 receptor agonist Liraglutide 3mg (Saxenda®) once-daily for weight management in forensic psychiatry; An Exploratory pilot study.

Summary

EudraCT number	2020-003718-11
Trial protocol	DK
Global end of trial date	01 September 2022

Results information

Result version number	v1 (current)
This version publication date	05 October 2023
First version publication date	05 October 2023

Trial information

Trial identification

Sponsor protocol code	AFJ2020-2
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04781998
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Mental Health Center Copenhagen, Frederiksberg
Sponsor organisation address	Hovedvejen 17, Frederiksberg, Denmark, 2000
Public contact	Anders Fink-Jensen, Mental Health Center Copenhagen, Frederiksberg, anders.fink-jensen@regionh.dk
Scientific contact	Anders Fink-Jensen, Mental Health Center Copenhagen, Frederiksberg, anders.fink-jensen@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	01 August 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 September 2022
Global end of trial reached?	Yes
Global end of trial date	01 September 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to investigate the effectiveness of pharmacological treatment with liraglutide 3 mg (Saxenda®) for bodyweight management in patients with diagnosed with severe mental illness and excess weight (BMI ≥ 27 kg/m²) who also have bodyweight related medical problems or with severe mental illness and obesity (BMI ≥ 30 kg/m²), admitted to a forensic psychiatry department. The primary endpoint is the number of patients completing the study defined as "completers".

Protection of trial subjects:

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy restrictions.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 November 2020
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: 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)	24
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited by investigators at departments for forensic psychiatry at Mental Health Centre Sct. Hans and Mental Health Centre Glostrup in Denmark

Pre-assignment

Screening details:

All patients were screened according to in- and exclusion criteria

Pre-assignment period milestones

Number of subjects started	24
Number of subjects completed	24

Period 1

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

Blinding implementation details:

Not blinded

Arms

Arm title	Baseline values
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Arm description:

Baseline

Arm type	Baseline
Investigational medicinal product name	Saxenda 6 mg/ml injektionsvæske, opløsning, i fyldt pen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled injector
Routes of administration	Subcutaneous use

Dosage and administration details:

Liraglutide 3 mg (Saxenda®) 6 mg/ml, 3 ml pre-filled pen-injector. Initial daily dose is 0.6 mg liraglutide (Saxenda®) for one week. If tolerated patients increase the dose by +0.6 mg each week until the full maintenance of 3 mg is reached.

Number of subjects in period 1	Baseline values
Started	24
Completed	24

Period 2	
Period 2 title	Overall periode
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	Intervention
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Arm description:

Liraglutide 3 mg (Saxenda®) 6 mg/ml, 3 ml pre-filled pen-injector. Initial daily dose is 0.6 mg liraglutide (Saxenda®) for one week. If tolerated patients increase the dose by +0.6 mg each week until the full maintenance of 3 mg is reached.

Arm type	Experimental
Investigational medicinal product name	Saxenda 6 mg/ml injektionsvæske, opløsning, i fyldt pen
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection in pre-filled injector
Routes of administration	Subcutaneous use

Dosage and administration details:

Liraglutide 3 mg (Saxenda®) 6 mg/ml, 3 ml pre-filled pen-injector. Initial daily dose is 0.6 mg liraglutide (Saxenda®) for one week. If tolerated patients increase the dose by +0.6 mg each week until the full maintenance of 3 mg is reached.

Number of subjects in period 2	Intervention
Started	24
Completed	11
Not completed	13
Consent withdrawn by subject	6
Discharge to another ward/home	3
Lost to follow-up	1
Coercive measures	1
Compliance	2

Baseline characteristics

Reporting groups

Reporting group title	Baseline
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Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	24	24	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Adults (18-65 years)	24	24	
Gender categorical			
Units: Subjects			
Female	5	5	
Male	19	19	

End points

End points reporting groups

Reporting group title	Baseline values
Reporting group description: Baseline	
Reporting group title	Intervention
Reporting group description: Liraglutide 3 mg (Saxenda®) 6 mg/ml, 3 ml pre-filled pen-injector. Initial daily dose is 0.6 mg liraglutide (Saxenda®) for one week. If tolerated patients increase the dose by +0.6 mg each week until the full maintenance of 3 mg is reached.	

Primary: Number of completers

End point title	Number of completers
End point description: A "completer" is defined as a participant with adherence to intervention defined as >80% throughout a full study duration (26 weeks)	
End point type	Primary
End point timeframe: Full study duration 26 weeks	

End point values	Baseline values	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	11		
Units: subjects	24	11		

Statistical analyses

Statistical analysis title	Categorical endpoint
Statistical analysis description: Categorical variables are presented as counts	
Comparison groups	Baseline values v Intervention
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon signed rank test

Secondary: Changes in body weight

End point title	Changes in body weight
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End point description:

End point type	Secondary
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End point timeframe:

26 weeks

End point values	Baseline values	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	10		
Units: Kg				
number (not applicable)	114.1	96.3		

Statistical analyses

Statistical analysis title	Continuous variables
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Statistical analysis description:

Continuous variables are presented as median. 26-week completion was tested using a binomial test with corresponding confidence intervals and changes in continuous variables were tested using Wilcoxon signed rank test.

Comparison groups	Baseline values v Intervention
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon signed rank test

Secondary: HbA1c

End point title	HbA1c
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End point description:

End point type	Secondary
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End point timeframe:

26 weeks

End point values	Baseline values	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	10		
Units: mmol/mol				
number (not applicable)	37	34.5		

Statistical analyses

Statistical analysis title	Continuous variables
Statistical analysis description: Continuous variables are presented as median. 26-week completion was tested using a binomial test with corresponding confidence intervals and changes in continuous variables were tested using Wilcoxon signed rank test.	
Comparison groups	Baseline values v Intervention
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon signed rank test

Secondary: Systolic blood pressure

End point title	Systolic blood pressure
End point description:	
End point type	Secondary
End point timeframe:	
26 weeks	

End point values	Baseline values	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	11		
Units: mmHg				
number (not applicable)	129	121		

Statistical analyses

Statistical analysis title	Continuous variables
Statistical analysis description: Continuous variables are presented as median. 26-week completion was tested using a binomial test with corresponding confidence intervals and changes in continuous variables were tested using Wilcoxon signed rank test.	
Comparison groups	Baseline values v Intervention

Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon signed rank test

Secondary: Heart rate

End point title	Heart rate
End point description:	
End point type	Secondary
End point timeframe:	
26 weeks	

End point values	Baseline values	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	11		
Units: beats/minute				
number (not applicable)	84	92		

Statistical analyses

Statistical analysis title	Continuous variables
Statistical analysis description:	
Continuous variables are presented as median. 26-week completion was tested using a binomial test with corresponding confidence intervals and changes in continuous variables were tested using Wilcoxon signed rank test.	
Comparison groups	Baseline values v Intervention
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon signed rank test

Secondary: Fibrosis 4 score (FIB-4 score)

End point title	Fibrosis 4 score (FIB-4 score)
End point description:	
End point type	Secondary
End point timeframe:	
26 weeks	

End point values	Baseline values	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	8		
Units: NA				
number (not applicable)	0.9	1.3		

Statistical analyses

Statistical analysis title	Continuous variables
Statistical analysis description:	
Continuous variables are presented as median. 26-week completion was tested using a binomial test with corresponding confidence intervals and changes in continuous variables were tested using Wilcoxon signed rank test.	
Comparison groups	Baseline values v Intervention
Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon signed rank test

Secondary: Cholesterol

End point title	Cholesterol
End point description:	
End point type	Secondary
End point timeframe:	
26 weeks	

End point values	Baseline values	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	11		
Units: mmol/l				
number (not applicable)	4.4	3.8		

Statistical analyses

Statistical analysis title	Continuous variables
Statistical analysis description:	
Continuous variables are presented as median. 26-week completion was tested using a binomial test with corresponding confidence intervals and changes in continuous variables were tested using Wilcoxon signed rank test.	
Comparison groups	Baseline values v Intervention
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon signed rank test

Secondary: Diastolic Blood pressure

End point title	Diastolic Blood pressure
End point description:	
End point type	Secondary
End point timeframe:	
26 weeks	

End point values	Baseline values	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	23	11		
Units: mmHg				
number (not applicable)	83	80		

Statistical analyses

Statistical analysis title	Continuous variables
Statistical analysis description:	
Continuous variables are presented as median. 26-week completion was tested using a binomial test with corresponding confidence intervals and changes in continuous variables were tested using Wilcoxon signed rank test.	
Comparison groups	Baseline values v Intervention
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon signed rank test

Secondary: LDL

End point title	LDL
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End point description:

End point type	Secondary
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End point timeframe:

26 weeks

End point values	Baseline values	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21	11		
Units: mmol/l				
number (not applicable)	2.7	1.9		

Statistical analyses

Statistical analysis title	Continuous variables
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Statistical analysis description:

Continuous variables are presented as median. 26-week completion was tested using a binomial test with corresponding confidence intervals and changes in continuous variables were tested using Wilcoxon signed rank test.

Comparison groups	Baseline values v Intervention
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon signed rank test

Secondary: HDL

End point title	HDL
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End point description:

End point type	Secondary
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End point timeframe:

26 weeks

End point values	Baseline values	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	11		
Units: mmol/l				
number (not applicable)	0.9	1.0		

Statistical analyses

Statistical analysis title	Continuous variables
Statistical analysis description: Continuous variables are presented as median. 26-week completion was tested using a binomial test with corresponding confidence intervals and changes in continuous variables were tested using Wilcoxon signed rank test.	
Comparison groups	Baseline values v Intervention
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon signed rank test

Secondary: Triglyceride

End point title	Triglyceride
End point description:	
End point type	Secondary
End point timeframe: 26 weeks	

End point values	Baseline values	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	11		
Units: mmol/l				
number (not applicable)	1.7	1.6		

Statistical analyses

Statistical analysis title	Continuous variables
Statistical analysis description: Continuous variables are presented as median. 26-week completion was tested using a binomial test with corresponding confidence intervals and changes in continuous variables were tested using Wilcoxon signed rank test.	
Comparison groups	Baseline values v Intervention

Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	Wilcoxon signed rank test

Adverse events

Adverse events information

Timeframe for reporting adverse events:

26 weeks (inclusion period). The patients will be informed about the opportunity to contact the investigator group in case of any events or reactions within 10 weeks after termination from the study.

Adverse event reporting additional description:

Serious adverse events occurring after a subject is discontinued from the study will NOT be reported unless the investigators feel that the event may have been caused by the study drug or a protocol procedure.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	None
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Dictionary version	0
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Reporting groups

Reporting group title	Intervention group (all participants)
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Reporting group description: -

Serious adverse events	Intervention group (all participants)		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 24 (12.50%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Psychiatric disorders			
Belt fixation			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Fractured hand			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Intervention group (all participants)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 24 (70.83%)		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 24 (12.50%)		
occurrences (all)	3		
Dizziness			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Feeling powerless			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Unspecific complains			
subjects affected / exposed	10 / 24 (41.67%)		
occurrences (all)	10		
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	4 / 24 (16.67%)		
occurrences (all)	4		
Diarrhoea			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Nausea			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
Vomiting			
subjects affected / exposed	2 / 24 (8.33%)		
occurrences (all)	2		
GERD			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	1 / 24 (4.17%)		
occurrences (all)	1		
Flatulence			

<p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 24 (4.17%)</p> <p>1</p>		
<p>Dry mouth</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 24 (4.17%)</p> <p>1</p>		
<p>meteorism</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 24 (4.17%)</p> <p>1</p>		
<p>Infections and infestations</p> <p>Infection</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 24 (4.17%)</p> <p>1</p>		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 June 2022	Patients receiving treatment with coercive measures were excluded from the trial. The possibility of re-entering the study and continuing study participation by signing a new informed consent after being excluded due to short (less than 48 hours) treatment with coercive measures, was approved in a protocol amendment after study initiation.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported