Clinical trial results:
Liraglutide Kidney:
A randomised, double-blinded, cross-over study investigating the short-term impact of liraglutide on kidney function in diabetic patients

Summary

EudraCT number	2012-003577-26
Trial protocol	DK
Global end of trial date	27 February 2014

Results information

Result version number	v1 (current)
This version publication date	06 July 2016
First version publication date	06 July 2016

Trial information

Trial identification

Sponsor protocol code	U1111-1131-5236

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01664676
WHO universal trial number (UTN)	U1111-1131-5236

Notes:

Sponsors

Sponsor organisation name	Aarhus University Hosptital, MEA
Sponsor organisation address	Noerrebrogade 44, Aarhus, Denmark, 8000
Public contact	Clinical Trial Information, Aarhus University Hosptital, MEA, 45 20894030, jsk@dadlnet.dk
Scientific contact	Clinical Trial Information, Aarhus University Hosptital, MEA, 45 20894030, jsk@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	27 February 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	27 February 2014
Global end of trial reached?	Yes
Global end of trial date	27 February 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the impact of a single dose liraglutide 1.2 mg on Glomerular Filtration Rate (GFR).

Protection of trial subjects:

Patients were moved internally in the hospital by wheeled transportation.

Background therapy:

Lithium tablets (16.2 mmol)
Isotonic NaCl infusion (100 ml/h)

Evidence for comparator: -	
Actual start date of recruitment	01 February 2013
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: 11
Worldwide total number of subjects	11
EEA total number of subjects	11

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)	11
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Key inclusion criteria: Male gender; T2D; metformin treatment; age 20–60 years; BMI 20–32 kg/m2.
Key exclusion criteria: Antidiabetic treatment other than metformin; HbA1c >8%; impaired liver or renal function; uncontrolled hypertension (>180/110mmHg); ≥3 types of antihypertensive drugs

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, Carer

Arms

Are arms mutually exclusive?	No
Arm title	Liraglutide

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Liraglutide
Investigational medicinal product code	
Other name	Victoza
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Single dose of 1.2 mg liraglutide subcutaneous in the abdomen

Arm title	Placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	Isotonic saline
Investigational medicinal product code	
Other name	Placebo
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Single dose of 1.2 mg placebo liraglutide (0.4 ml isotonic saline) subcutaneous in the abdomen

Number of subjects in period 1	Liraglutide	Placebo
Started	11	11
Completed	11	11

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	11	11	
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	54		
standard deviation	± 5	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	11	11	

End points

End points reporting groups	
Reporting group title	Liraglutide
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Change in GFR between liraglutide and placebo arm	
End point title	Change in GFR between liraglutide and placebo arm
End point description:	
End point type	Primary
End point timeframe:	
10 to 15h after liraglutide or place-liraglutide sc. injection	

End point values	Liraglutide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	11		
Units: ml/min				
arithmetic mean (standard deviation)	104.6 (± 9.9)	106.2 (± 11.5)		

Statistical analyses

Statistical analysis title	Change in GFR, t-test
Comparison groups	Liraglutide v Placebo
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.55
Method	t-test, 2-sided

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
First patient first visit to last patient last visit	
Adverse event reporting additional description:	
We did not experience any AE either non-serious or serious.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	14

Frequency threshold for reporting non-serious adverse events: 1 %

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: We did not experience any AE either serious og non-serious

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/26910107