Clinical trial results:
Effect of the GLP-1 receptor agonist exenatide on impaired hypoglycaemic awareness in type 1 diabetes

Summary

EudraCT number	2016-000790-21
Trial protocol	NL
Global end of trial date	03 January 2018

Results information

Result version number	v1 (current)
This version publication date	04 January 2020
First version publication date	04 January 2020
Summary attachment (see zip file)	Paper effect of GLP-1 receptor agonist on IAH (Effect of GLP-1 receptor agonist exenatide on IAH in type 1 diabetes.pdf)

Trial information

Trial identification

Sponsor protocol code	ESR-15-10862

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02735031
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Radboudumc
Sponsor organisation address	PO Box 9101, Nijmegen, Netherlands,
Public contact	Lian van Meijel, Radboudumc, 31 243613286, Lian.vanMeijel@radboudumc.nl
Scientific contact	Lian van Meijel, Radboudumc, 31 243613286, Lian.vanMeijel@radboudumc.nl

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	03 January 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	03 January 2018
Global end of trial reached?	Yes
Global end of trial date	03 January 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effect of treatment with the GLP-1ra exenatide on the awareness of and counterregulatory hormone responses to hypoglycaemia in people with type 1 diabetes and impaired hypoglycaemic awareness

Protection of trial subjects:

All the data collected for this study was coded by a unique identification code.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 September 2016
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	Netherlands: 10
Worldwide total number of subjects	10
EEA total number of subjects	10

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)	10
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited between January 2017 and November 2017, with a follow-up period between February 2017 and March 2018

Pre-assignment

Screening details:

Inclusion criteria:
- Type 1 diabetes, disease duration ≥ 1 year
- Age: 18-70 years
- Insulin treatment according to basal-bolus insulin regimen (injections or insulin pump)
- Body-Mass Index: 19-40 kg/m2
- Glycated hemoglobin (HbA1c)

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

Arms

Are arms mutually exclusive?	No
Arm title	Exenatide

Arm description: -

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

Dosage and administration details:

5 microgram twice daily

Arm title	Placebo

Arm description: -

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

Dosage and administration details:

5 microgram twice daily

Number of subjects in period 1	Exenatide	Placebo
Started	10	10
Completed	10	10

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	10	10	
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)	10	10	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	6	6	
Male	4	4	

End points

End points reporting groups

Reporting group title	Exenatide
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Symptom score in response to hypoglycemia

End point title	Symptom score in response to hypoglycemia
End point description:	
End point type	Primary
End point timeframe:	
Five timepoints during hypoglycemic clamps (baseline, after 30 min of euglycemia, twice during hypoglycemia (after 20 and 40 min) and 45 minutes after recovery from hypoglycemia)	

End point values	Exenatide	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: points	10	10		

Statistical analyses

Statistical analysis title	Paired samples t-test
Comparison groups	Exenatide v Placebo
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	≤ 0.05
Method	t-test, 2-sided

Adverse events

Adverse events information	
Timeframe for reporting adverse events: January 2017 and March 2018	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	SNOMED CT
Dictionary version	1

Reporting groups	
Reporting group title	All participants

Reporting group description: -

Serious adverse events	All participants		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	All participants		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 10 (30.00%)		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 October 2017	Change of inclusion criterion, from 18-70 years to 18-75 years old

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported