Clinical trial results:
The effect of Exenatide on brown adipose tissue activity and energy expenditure in healthy young men

Summary

EudraCT number	2016-000238-23
Trial protocol	NL
Global end of trial date	30 January 2018

Results information

Result version number	v1 (current)
This version publication date	21 February 2020
First version publication date	21 February 2020

Trial information

Trial identification

Sponsor protocol code	ExeBAT01

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03002675
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Leiden University Medical Center
Sponsor organisation address	Albinusdreef 2, Leiden, Netherlands, 2333ZA
Public contact	Clinical trial information, Leiden University Medical Center, l.g.m.janssen@lumc.nl
Scientific contact	Clinical trial information, Leiden University Medical Center, l.g.m.janssen@lumc.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	30 January 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 January 2018
Global end of trial reached?	Yes
Global end of trial date	30 January 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of Exenatide treatment on BAT activity and energy expenditure in healthy young subjects of South Asain and white Caucasian descent

Protection of trial subjects:

NA

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 2016
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	Netherlands: 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: -

Pre-assignment

Screening details:

Inclusion Criteria
- Dutch South Asian or white Caucasian male, 20-36 years
- BMI ≥ 18 and ≤ 27 kg/m2
- Good general health

Period 1

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

Arms

Arm title	exenatide

Arm description: -

Arm type	exenatide
Investigational medicinal product name	exenatide (Bydureon)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

2mg

Number of subjects in period 1	exenatide
Started	24
Completed	24

Period 2

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

Arms

Arm title	exenatide
Arm description: -	
Arm type	exenatide
Investigational medicinal product name	exenatide (Bydureon)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

2mg

Number of subjects in period 2	exenatide
Started	24
Completed	24

Baseline characteristics

Reporting groups	
Reporting group title	baseline

Reporting group description: -

Reporting group values	baseline	Total	
Number of subjects	24	24	
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	26.5		
standard deviation	± 0.7	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	24	24	

End points

End points reporting groups	
Reporting group title	exenatide
Reporting group description: -	
Reporting group title	exenatide
Reporting group description: -	

Primary: energy expenditure	
End point title	energy expenditure
End point description:	
End point type	Primary
End point timeframe: after 12 weeks exenatide treatment	

End point values	exenatide	exenatide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	24		
Units: kcal/day				
number (not applicable)	24	24		

Attachments (see zip file)	20200204 eudract_exe_calorimetry.pdf

Statistical analyses

Statistical analysis title	exenatide_calorimetry
Comparison groups	exenatide v exenatide
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	> 0.05
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-102
upper limit	15

Notes:
[1] - Data were analysed by linear mixed models and are presented as mean±SEM.

Primary: bat fdg uptake

End point title	bat fdg uptake
End point description:	
End point type	Primary
End point timeframe:	
12 weeks exenatide	

End point values	exenatide	exenatide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	24		
Units: NA	24	24		

Attachments (see zip file)	20200204 eudract_exe_bat_pet.pdf

Statistical analyses

Statistical analysis title	fdg uptake bat
Comparison groups	exenatide v exenatide
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	42

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 12 weeks exenatide	
Assessment type	Systematic
Dictionary used	
Dictionary name	NA
Dictionary version	1
Reporting groups	
Reporting group title	total study population

Reporting group description: -

Serious adverse events	total study population		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 24 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	total study population		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 24 (75.00%)		
Nervous system disorders			
Dizziness	Additional description: Flu-like symptoms, fatigue, asthenia, headache, dizziness		
subjects affected / exposed	6 / 24 (25.00%)		
occurrences (all)	6		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	12 / 24 (50.00%)		
occurrences (all)	12		
Dyspepsia	Additional description: obstipation, diarrhea, dyspepsia, abdominal distention, reflux		
subjects affected / exposed	3 / 24 (12.50%)		
occurrences (all)	3		
Skin and subcutaneous tissue disorders			

subcutaneous infiltrate			
subjects affected / exposed	18 / 24 (75.00%)		
occurrences (all)	18		
Erythema	Additional description: erythema, rash, pruritus, hematoma		
subjects affected / exposed	6 / 24 (25.00%)		
occurrences (all)	6		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 October 2016	adjust cooling protocol
26 January 2017	add questionnaires
24 August 2017	expand bmi and age inclusion criteria

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported