Clinical trial results:
Acyl and desacyl ghrelin: The Yin and Yang of glucose homeostasis and insulin sensitivity?
-Acute metabolic effects of desacyl ghrelin in insulin resistant patients

Summary

EudraCT number	2013-000022-63
Trial protocol	DK
Global end of trial date	08 December 2018

Results information

Result version number	v1 (current)
This version publication date	01 February 2020
First version publication date	01 February 2020

Trial information

Trial identification

Sponsor protocol code	1-10-72-393-12

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Aarhus University
Sponsor organisation address	Palle Juel Jensens Boulevard, Aarhus N, Denmark, 8200
Public contact	Esben T Vestergaard, Aarhus University, 45 78461631,
Scientific contact	Esben T Vestergaard, Aarhus University, 45 78461631,

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 December 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 December 2017
Global end of trial reached?	Yes
Global end of trial date	08 December 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The main objective of the trial is to investigate the effects of desacyl ghrelin on insulin resistance

Protection of trial subjects:

Measurement of haematological, inflammation, kidney function, liver function, HbA1c, plasma glucose, and thyroid parameters. Clinical examination incl. blood pressure and pulse measurements.

Background therapy:

None.

Evidence for comparator:

N/A.

Actual start date of recruitment	01 April 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: 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:

Recruitment period April 2014 to February 2015.
Region: Denmark.
Criteria:
- men with type 2 diabetes according to ADA, Standards of Medical Care in Diabetes, 2011. Diabetes Care. 2011 January 1, 2011;34(Supplement 1):S11-S61.
- age 18-65 years
- HbA1c < 11 %

Pre-assignment

Screening details:

Criteria:
- men with type 2 diabetes according to ADA, Standards of Medical Care in Diabetes, 2011. Diabetes Care. 2011 January 1, 2011;34(Supplement 1):S11-S61.
- age 18-65 years
- HbA1c < 11 %

12 subjects were screened, 1 fulfiled exclusion criteria (IHD) and 1 decided not to participate.
None significant events were observed.

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	Investigator, Monitor, Subject, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	No
Arm title	Unacylated ghrein

Arm description:

UAG infusion (DAG 1.0 µg/kg/h i.v.)

Arm type	Active comparator
Investigational medicinal product name	Unacylated ghrelin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intravenous drip use

Dosage and administration details:

1.0 µg/kg/h i.v.,

Arm title	Placebo

Arm description:

Isotonic saline

Arm type	Placebo
Investigational medicinal product name	Isotonic saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous drip use

Dosage and administration details:

0.9% saline.

Number of subjects in period 1	Unacylated ghrein	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	
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			
39-60 years			
Units: years			
arithmetic mean	52.4		
full range (min-max)	39 to 60	-	
Gender categorical Units: Subjects			
Female	0	0	
Male	10	10	
Ethnic group			
Caucasians			
Units: Subjects			
Ethnic group	10	10	

End points

End points reporting groups	
Reporting group title	Unacylated ghrein
Reporting group description: UAG infusion (DAG 1.0 µg/kg/h i.v.)	
Reporting group title	Placebo
Reporting group description: Isotonic saline	

Primary: Insulin sensitivity	
End point title	Insulin sensitivity
End point description:	
End point type	Primary
End point timeframe: April 2014-February 2015	

End point values	Unacylated ghrein	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	10	10		
Units: mg glucose/kg body weight pr minute				
arithmetic mean (standard error)	4.69 (± 0.56)	4.98 (± 0.43)		

Statistical analyses

Statistical analysis title	paired t-test
Comparison groups	Unacylated ghrein v Placebo
Number of subjects included in analysis	20
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.66
Method	t-test, 2-sided

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

April 2014-February 2015

Assessment type	Non-systematic

Dictionary used

Dictionary name	Own database
Dictionary version	1

Reporting groups

Reporting group title	Overall trial

Reporting group description:

All included subjects.

Serious adverse events	Overall trial		
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	0		

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

Non-serious adverse events	Overall trial		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 10 (0.00%)		

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: Wi did not experience any adverse events at all.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/30722063