

**Clinical trial results:
Dasiglucagon in the treatment of postprandial hypoglycaemia after
Roux-en-Y gastric bypass****Summary**

EudraCT number	2019-001915-22
Trial protocol	DK
Global end of trial date	26 February 2020

Results information

Result version number	v1 (current)
This version publication date	31 March 2021
First version publication date	31 March 2021

Trial information**Trial identification**

Sponsor protocol code	CKN-DASI-RYGB
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03984370
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Center for Clinical Metabolic Research at Gentofte Hospital
Sponsor organisation address	Gentofte Hospitalsvej 7, hall 7, 3rd floor, Hellerup, Denmark, 2900
Public contact	Herlev-Gentofte Hospital, Center for Clinical Metabolic Research at Herlev-Gentofte Hospital, +45 60117434, casper.kjaersgaard.nielsen@regionh.dk
Scientific contact	Herlev-Gentofte Hospital, Center for Clinical Metabolic Research at Herlev-Gentofte Hospital, +45 60117434, casper.kjaersgaard.nielsen@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	26 February 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 February 2020
Global end of trial reached?	Yes
Global end of trial date	26 February 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This was a proof-of-concept study aiming to evaluate the use of dasiglucagon in the management of postprandial hyperinsulinaemic hypoglycaemia in RYGB-operated individuals. To examine the effects of two different doses of dasiglucagon on the postprandial nadir plasma glucose concentration in RYGB-operated individuals suffering from postprandial hyperinsulinaemic hypoglycaemia by use of a mixed meal test (MMT).

The study was designed as a double-blinded, randomised, placebo-controlled, 3-period, 3-treatment, crossover study comprising 3 separate treatment days (MMTs).

Protection of trial subjects:

Participants are offered a healthy lunch followed by a 30-minute observation period after completion of each MMTs.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 September 2019
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: 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)	9

From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

- Oral and written information about the study.
- Oral and written informed consent.
- Review of inclusion and exclusion criteria.
- Measurement of blood pressure, pulse, weight and height.
- Fasting blood samples analysis including for, anaemia: basophilocytes, eosinophilocytes, erythrocytes, ferritin, haemoglobin, folate, iron, leukocytes, lymph

Pre-assignment

Screening details:

A physician evaluated if inclusion criteria were fulfilled before enrollment

Period 1

Period 1 title	Overall (placebo, 80 and 200 ug dasiglu) (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

Blinding procedure was successful

Arms

Are arms mutually exclusive?	No
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Arm title	Placebo
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Arm description: -

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

Dosage and administration details:

0,4 mL of placebo

Arm title	80 ug dasiglucagon
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Dasiglucagon
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

80 ug dasiglucagon s.c. in abdomen

Arm title	200 ug dasiglucagon
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Arm description: -

Arm type	Experimental
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Investigational medicinal product name	Dasiglucagon
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:
200 ug dasiglucagon s.c. in abdomen

Number of subjects in period 1	Placebo	80 ug dasiglucagon	200 ug dasiglucagon
Started	10	10	10
Completed	10	10	10

Baseline characteristics

Reporting groups

Reporting group title	Overall (placebo, 80 and 200 ug dasiglu)
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Reporting group description:

10 subjects at the baseline

Reporting group values	Overall (placebo, 80 and 200 ug dasiglu)	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)	9	9	
From 65-84 years	1	1	
85 years and over	0	0	
Gender categorical			
Units: Subjects			
Female	8	8	
Male	2	2	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	-
Reporting group title	80 ug dasiglucagon
Reporting group description:	-
Reporting group title	200 ug dasiglucagon
Reporting group description:	-

Primary: Nadir plasma glucose concentration

End point title	Nadir plasma glucose concentration
End point description:	
End point type	Primary
End point timeframe:	Nadir plasma glucose concentration within 240 minutes after MMT.

End point values	Placebo	80 ug dasiglucagon	200 ug dasiglucagon	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	10 ^[1]	10 ^[2]	10 ^[3]	
Units: mmol/l				
arithmetic mean (standard error)	3.0 (± 0.2)	3.9 (± 0.3)	4.5 (± 0.3)	

Notes:

[1] - placebo

[2] - 80 ug

[3] - 200 ug

Attachments (see zip file)	Nadir glucose concentration/Nadir.pdf
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Statistical analyses

Statistical analysis title	Pla vs. 200 ug
Statistical analysis description:	A mixed model with Sidak corrections for multiple comparisons
Comparison groups	Placebo v 200 ug dasiglucagon
Number of subjects included in analysis	20
Analysis specification	Post-hoc
Analysis type	
P-value	< 0.001
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	1.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	2.05

Statistical analysis title	Pla vs. 80 ug
Statistical analysis description: A mixed model with Sidak corrections for multiple comparisons	
Comparison groups	Placebo v 80 ug dasiglucagon
Number of subjects included in analysis	20
Analysis specification	Post-hoc
Analysis type	other
P-value	< 0.01 [4]
Method	ANOVA
Parameter estimate	Mean difference (final values)
Point estimate	0.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.35
upper limit	1.35

Notes:

[4] - Sidak corrected

Adverse events

Adverse events information

Timeframe for reporting adverse events:

0-240 during the MMts

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23
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Reporting groups

Reporting group title	All adverse events
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Reporting group description: -

Serious adverse events	All adverse events		
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	All adverse events		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 10 (40.00%)		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	3 / 10 (30.00%)		
occurrences (all)	3		
Headache			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	2 / 10 (20.00%)		
occurrences (all)	2		

Dizziness			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		
Sweatiness			
subjects affected / exposed	1 / 10 (10.00%)		
occurrences (all)	1		

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