



## Clinical trial results:

### Effect of glucagon-like peptide 1 (GLP-1) based diabetes medication on blood flow velocity in ischemic stroke patients

#### Summary

EudraCT number	2016-001219-18
Trial protocol	DK
Global end of trial date	06 May 2023

#### Results information

Result version number	v1 (current)
This version publication date	05 November 2025
First version publication date	05 November 2025

#### Trial information

##### Trial identification

Sponsor protocol code	E.G.R.A.B.I.S1
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02829502
WHO universal trial number (UTN)	-

Notes:

#### Sponsors

Sponsor organisation name	Herlev Gentofte Hospital
Sponsor organisation address	Borgmester Ib Juuls Vej 1, Herlev, Denmark,, Herlev, Denmark, 2730
Public contact	Christina Rostrup Kruuse, Herlev Gentofte Hospital, 45 38681233, christina.rostrup.kruuse@regionh.dk
Scientific contact	Christina Rostrup Kruuse, Herlev Gentofte Hospital, 45 38681233, christina.rostrup.kruuse@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:

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**Results analysis stage**

Analysis stage	Final
Date of interim/final analysis	27 February 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	06 May 2023
Global end of trial reached?	Yes
Global end of trial date	06 May 2023
Was the trial ended prematurely?	Yes

Notes:

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**General information about the trial**

Main objective of the trial:

The main objective is to investigate the effect of a single dose of 5 mikrogram GLP-1 receptor agonist ( exenatide) on cerebral and peripheral arterial function in individuals with ischemic stroke.

Protection of trial subjects:

During the trial, participants were monitored hourly for heart rate and blood pressure. They were also asked about their general well-being and the occurrence of any side effects on an hourly basis. After completing the trial days, participants filled out a side effect form, which was then submitted to the investigator. Participants who were discharged from the department were provided with the phone number of the Department of Neurology, Herlev Gentofte Hospital (the sponsor), which they could call if they experienced any side effects or encountered any other issues.

Background therapy:

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Evidence for comparator:

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Actual start date of recruitment	01 April 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

Country: Number of subjects enrolled	Denmark: 27
Worldwide total number of subjects	27
EEA total number of subjects	27

Notes:

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**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)	16

From 65 to 84 years	11
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Individuals with ischemic stroke were recruited from the stroke unit of the Department of Neurology, Copenhagen University Hospital – Herlev and Gentofte, Copenhagen, Denmark. Individuals were recruited between November 2016 and May 2023.

### Pre-assignment

Screening details:

A medical doctor or student did the screening.

Criteria: individuals aged 18 years or above, clinical and radiological confirmed ischemic stroke diagnosis. Could receive GLP-1-RA or placebo within 21 days of stroke onset. A NIHSS score between 1-20 at admission, a mRS score of 2 or lower, and capacity to provide informed consent.

### 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

Blinding implementation details:

A single subcutaneous dose of 5 µg (0.05 mL) exenatide (Byetta® Pen Injector, AstraZeneca) or a subcutaneous placebo (0.9% saline water, 0.05 mL) was administered. During administration, a registered nurse, not otherwise involved in the trial, administered the medication or placebo. Individuals with ischemic stroke were blindfolded and the investigator left the room during treatment being administered.

### Arms

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Exenatide

Arm description:

Parallel-arm trial. Exenatide (5 ug) was given as a single dose.

Arm type	Experimental
Investigational medicinal product name	Exenatide
Investigational medicinal product code	
Other name	Byetta
Pharmaceutical forms	Suspension for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

Dosage: 5 micrograms (ug) Administration details: Sub-cutaneous injection by pen

<b>Arm title</b>	Placebo
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Arm description:

Placebo (0.9% saline water) was given subcutaneously by a small syringe

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

Dosage and administration details:

0.9% saline water, 0.05 mL

<b>Number of subjects in period 1</b>	Exenatide	Placebo
Started	13	14
Completed	13	14

## Baseline characteristics

### Reporting groups

Reporting group title

Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	27	27	
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			
median	61		
inter-quartile range (Q1-Q3)	56 to 69.5	-	
Gender categorical			
Units: Subjects			
Female	2	2	
Male	25	25	

## End points

### End points reporting groups

Reporting group title	Exenatide
Reporting group description: Parallel-arm trial. Exenatide (5 ug) was given as a single dose.	
Reporting group title	Placebo
Reporting group description: Placebo (0.9% saline water) was given subcutaneously by a small syringe	
Subject analysis set title	Exenatide - baseline
Subject analysis set type	Sub-group analysis
Subject analysis set description: Exenatide group at baseline	
Subject analysis set title	Exenatide - 180 minutes
Subject analysis set type	Sub-group analysis
Subject analysis set description: Exenatide group at 180 minutes	
Subject analysis set title	Placebo - baseline
Subject analysis set type	Sub-group analysis
Subject analysis set description: Placebo group at baseline	
Subject analysis set title	Placebo - 180 minutes
Subject analysis set type	Sub-group analysis
Subject analysis set description: Placebo group at 180 minutes	

### Primary: Near-infrared spectroscopy (NIRS)

End point title	Near-infrared spectroscopy (NIRS)
End point description: Changes in brain oxygen saturation before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.	
End point type	Primary
End point timeframe: We performed NIRS measurements at baseline and 180 minutes post-medication.	

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: rSO (%)				
arithmetic mean (standard deviation)	69.1 (± 4.9)	71.2 (± 6.4)	67.9 (± 6.4)	71.0 (± 4.8)

### Statistical analyses

<b>Statistical analysis title</b>	T-test
Statistical analysis description: We performed a paired sample T-test.	
Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

## Secondary: Blood pressure - systolic

End point title	Blood pressure - systolic
End point description: Changes in blood pressure before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.	
End point type	Secondary
End point timeframe: We performed blood pressure measurements at baseline and 180 minutes post-medication.	

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: mmHg				
arithmetic mean (standard deviation)	145.0 (± 20.1)	151.5 (± 18.3)	141.7 (± 19.3)	147.1 (± 21.5)

## Statistical analyses

<b>Statistical analysis title</b>	T-test
Statistical analysis description: Paired sample t-test	
Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided



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**Secondary: Blood pressure - diastolic**

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End point title	Blood pressure - diastolic
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End point description:

Changes in blood pressure before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.

End point type	Secondary
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End point timeframe:

We performed blood pressure measurements at baseline and 180 minutes post-medication.

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End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: mmHg				
arithmetic mean (standard deviation)	83.8 (± 6.5)	84.6 (± 7.7)	88.0 (± 12.8)	90.9 (± 12.0)

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**Statistical analyses**

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Statistical analysis title	T-test
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Statistical analysis description:

We performed a paired sample t-test

Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
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Number of subjects included in analysis	54
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Analysis specification	Pre-specified
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Analysis type	other
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P-value	< 0.05
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Method	t-test, 2-sided
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**Secondary: EndoPat - Regional hyperaemia index (RHI)**

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End point title	EndoPat - Regional hyperaemia index (RHI)
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End point description:

Changes in regional hyperemia index before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.

End point type	Secondary
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End point timeframe:

We performed EndoPAT measurements at baseline and after 180 minutes post-medication.

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End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11	11	12	12
Units: no unit				
arithmetic mean (standard deviation)	2.3 ( $\pm$ 0.6)	2.6 ( $\pm$ 1.0)	1.9 ( $\pm$ 0.5)	2.1 ( $\pm$ 0.5)

## Statistical analyses

Statistical analysis title	T-test
Statistical analysis description: paired sample t-test	
Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

## Secondary: EndoPat - augmentation index standardized to a heart rate of 75 (AI@75)

End point title	EndoPat - augmentation index standardized to a heart rate of 75 (AI@75)
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End point description:

Changes in EndoPAT - augmentation index standardized to a heart rate of 75 before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.

End point type	Secondary
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End point timeframe:

We performed EndoPAT measurements at baseline and after 180 minutes post-medication.

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	11	11	12	12
Units: %				
arithmetic mean (standard deviation)	21.8 ( $\pm$ 17.6)	20.8 ( $\pm$ 15.5)	12.3 ( $\pm$ 19.3)	14.3 ( $\pm$ 17.4)

## Statistical analyses

<b>Statistical analysis title</b>	T-test
Statistical analysis description: paired sample t-test	
Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

## Secondary: Ankle brachial index

End point title	Ankle brachial index
End point description: Changes in ankle brachial index before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.	
End point type	Secondary
End point timeframe: We performed ankle brachial index measurements at baseline and after 180 minutes post-medication.	

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: No unit				
arithmetic mean (standard deviation)	1.1 (± 0.1)	1.1 (± 0.1)	1.1 (± 0.1)	1.1 (± 0.2)

## Statistical analyses

<b>Statistical analysis title</b>	T-test
Statistical analysis description: We performed a paired sample T-test.	
Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

## Secondary: Plasma glucose

End point title	Plasma glucose
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End point description:

Changes in plasma glucose before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.

End point type	Secondary
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End point timeframe:

Plasma glucose were collected at baseline 180 minutes post-medication.

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: mmol/L				
arithmetic mean (standard deviation)	5.8 (± 0.7)	4.9 (± 0.3)	5.8 (± 0.4)	5.5 (± 0.4)

## Statistical analyses

Statistical analysis title	T-test
Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

## Secondary: Insulin

End point title	Insulin
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End point description:

Changes in insulin concentraton before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at different timepoints.

End point type	Secondary
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End point timeframe:

We performed insulin measurements at baseline and 180 minutes postmedication.

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: pmol/L				
arithmetic mean (standard deviation)	58.2 (± 34.5)	56.1 (± 48.2)	81.0 (± 43.7)	61.5 (± 37.2)

## Statistical analyses

Statistical analysis title	T-test
Statistical analysis description: paired sample t-test	
Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

## Secondary: C-peptide

End point title	C-peptide
End point description: Blood c-peptide before exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at baseline.	
End point type	Secondary
End point timeframe: We performed blood c-peptide measurments at baseline and 180 minutes post-medication	

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: pmol/L				
arithmetic mean (standard deviation)	733.8 (± 307.7)	695.2 (± 363.5)	843.8 (± 345.0)	726.0 (± 294.1)

## Statistical analyses

Statistical analysis title	T-test
Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo -

	baseline v Placebo - 180 minutes
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

### Secondary: Blood sample - TNF

End point title	Blood sample - TNF
End point description: Changes in biomarker concentration before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.	
End point type	Secondary
End point timeframe: Blood samples were collected at baseline and after 180 minutes post-medication.	

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: pg/mL				
arithmetic mean (standard deviation)	1.992 (± 0.431)	2.276 (± 1.122)	1.793 (± 0.707)	1.985 (± 0.829)

### Statistical analyses

Statistical analysis title	T-test
Statistical analysis description: paired sample t-test	
Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

### Secondary: Blood sample - IL-6

End point title	Blood sample - IL-6
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End point description:

Changes in biomarker concentration before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.

End point type	Secondary
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End point timeframe:

Blood samples were collected at baseline and after 180 minutes post-medication.

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: pg/mL				
arithmetic mean (standard deviation)	2.846 (± 3.173)	3.372 (± 2.629)	2.742 (± 3.199)	3.536 (± 4.025)

## Statistical analyses

Statistical analysis title	T-test
Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

## Secondary: Blood sample - IL-1beta

End point title	Blood sample - IL-1beta
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End point description:

Changes in biomarker concentration before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.

End point type	Secondary
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End point timeframe:

Blood samples were collected at baseline and after 180 minutes post-medication.

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: pg/mL				
arithmetic mean (standard deviation)	0.516 ( $\pm$ 0.298)	0.315 ( $\pm$ 0.332)	0.220 ( $\pm$ 0.178)	0.760 ( $\pm$ 1.406)

## Statistical analyses

Statistical analysis title	T-test
Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

## Secondary: Blood sample - VCAM1

End point title	Blood sample - VCAM1
End point description:	Changes in biomarker concentration before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.
End point type	Secondary
End point timeframe:	Blood samples were collected at baseline and after 180 minutes post-medication.

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: ng/mL				
arithmetic mean (standard deviation)	3262963 ( $\pm$ 3191765)	2744889 ( $\pm$ 2338746)	1979060 ( $\pm$ 1463873)	1766864 ( $\pm$ 1318127)

## Statistical analyses

Statistical analysis title	T-test
Statistical analysis description:	paired sample t-test



Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

### Secondary: Blood sample - ICAM-1

End point title	Blood sample - ICAM-1
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End point description:

Changes in biomarker concentration before and after exenatide/placebo for each subject were calculated and then further used for statistical analysis. Here, results are shown as the mean value and standard deviation for both groups at the different timepoints.

End point type	Secondary
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End point timeframe:

Blood samples were collected at baseline and after 180 minutes post-medication.

End point values	Exenatide - baseline	Exenatide - 180 minutes	Placebo - baseline	Placebo - 180 minutes
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	13	13	14	14
Units: ng/mL				
arithmetic mean (standard deviation)	2626802 (± 2472003)	2162964 (± 1757315)	1724145 (± 1183808)	1622428 (± 1159442)

### Statistical analyses

Statistical analysis title	T-test
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Statistical analysis description:

paired sample t-test

Comparison groups	Exenatide - baseline v Exenatide - 180 minutes v Placebo - baseline v Placebo - 180 minutes
Number of subjects included in analysis	54
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.05
Method	t-test, 2-sided

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

During the whole trial period.

Adverse event reporting additional description:

Questionnaire given to participants. Participants were asked to note all adverse events for 24 hours after medication administration.

Assessment type	Systematic
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### Dictionary used

Dictionary name	Events not coded
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Dictionary version	N/A
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### Reporting groups

Reporting group title	Exenatide
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Reporting group description:

Exenatide (5 ug), single dose.

Reporting group title	Placebo
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Reporting group description: -

Serious adverse events	Exenatide	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)	0 / 14 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0.05 %

Non-serious adverse events	Exenatide	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 13 (61.54%)	7 / 14 (50.00%)	
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 13 (15.38%)	3 / 14 (21.43%)	
occurrences (all)	2	3	
Dizziness			
subjects affected / exposed	3 / 13 (23.08%)	4 / 14 (28.57%)	
occurrences (all)	3	4	
General disorders and administration site conditions			

Weakness/fatigue subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	1 / 14 (7.14%) 1	
Gastrointestinal disorders			
Nausea subjects affected / exposed occurrences (all)	3 / 13 (23.08%) 3	1 / 14 (7.14%) 1	
Bloating subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 14 (0.00%) 0	
Acid reflux subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 14 (0.00%) 0	
Flatulence subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	2 / 14 (14.29%) 2	

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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### Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
01 May 2018	IPeriod where the trial was inactive due to nvestigator change	02 August 2020
21 March 2020	COVID-19 pandemic, which posed challenges for recruitment due to social distancing measures, resulting in delays in the study timeline.	01 February 2021

Notes:

### Limitations and caveats

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

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Notes: