Clinical trial results:
Treatment of hypoglycemia following gastric bypass surgery

Summary

EudraCT number	2015-001086-50
Trial protocol	DK
Global end of trial date	08 April 2017

Results information

Result version number	v1 (current)
This version publication date	06 April 2020
First version publication date	06 April 2020

Trial information

Trial identification

Sponsor protocol code	HypoGB2015

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Dorte Lindqvist Hansen
Sponsor organisation address	lykkevækvej 1, Køge, Denmark, 4600
Public contact	Caroline Christfort Gormsen, Køge Sygehus, cacg@regionsjaelland.dk
Scientific contact	Caroline Christfort Gormsen, Køge Sygehus, cacg@regionsjaelland.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	01 September 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	08 April 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To study the effects of 5 different pharmacological treatments on glucosemetabolism in patients with postprandial hypoglycemia following gastric bypass surgery.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2015
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: 11
Worldwide total number of subjects	11
EEA total number of subjects	11

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)	11
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment was performed as planned, although it was not possible to recruit the planned number of 16 participants within the given time period for the study conduction, and thus, only 11 participants were included in the study.

Pre-assignment

Screening details:

At screening, all participants underwent at 6-day continuous glucose monitoring (CGM) to verify postprandial hypoglycemia. Furthermore, participants were examined for fasting hypoglycemia, fasting hyperinsulinemia and anemia.

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Blinding was not perfomed due to different formulations and dosage frequencies of the studied therapeutics

Arms

Are arms mutually exclusive?	No
Arm title	Baseline

Arm description:

The baseline arm consisted of a 6-day CGM recording and a mixed meal tolerance test (MMT) without treatment intervention.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Acarbose

Arm description:

Participants completed 1 week treatment with acarbose 50 mg at every meal together with CGM. After 1 week treatment, participants underwent a MMT.

Arm type	Experimental
Investigational medicinal product name	acarbose
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

50 mg administered at every meal for 7 days.

Arm title	Sitagliptin

Arm description:

Participants completed 1 week treatment with sitagliptin 100 mg once daily together with CGM. After 1 week treatment, participants underwent a MMT.

Arm type	Experimental
Investigational medicinal product name	sitagliptin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

100 mg taken once daily for 7 days.

Arm title	Verapamil

Arm description:

Participants completed 1 week treatment with verapamil 120 mg once daily together with CGM. After 1 week treatment, participants underwent a MMT.

Arm type	Experimental
Investigational medicinal product name	verapamil
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

120 mg taken once daily for 7 days.

Arm title	Liraglutide

Arm description:

Participants completed three weeks treatment with liraglutide, titrated from 0.6 to 1.2 mg once daily. During the last week of liraglutide treatment, participants also wore CGM. After the three weeks treatment period, participants underwent a MMT.

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

Dosage and administration details:

0.6 mg once daily for 7 days and then 1.2 mg once daily for 14 days.

Arm title	Pasireotide

Arm description:

Participants received a 300 ug pasireotide injection 30 minutes prior to a MMT.

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

Dosage and administration details:

300 ug given as a single dose prior to a mixed meal tolerance test.

Number of subjects in period 1	Baseline	Acarbose	Sitagliptin
Started	11	11	11
Completed	11	10	11
Not completed	0	1	0
Adverse event, non-fatal	-	1	-

Number of subjects in period 1	Verapamil	Liraglutide	Pasireotide
Started	11	11	11
Completed	11	11	11
Not completed	0	0	0
Adverse event, non-fatal	-	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Overall study

Reporting group description: -

Reporting group values	Overall study	Total	
Number of subjects	11	11	
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)	11	11	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	45		
standard deviation	± 8	-	
Gender categorical Units: Subjects			
Female	11	11	
Male	0	0	

End points

End points reporting groups

Reporting group title	Baseline
Reporting group description:	
The baseline arm consisted of a 6-day CGM recording and a mixed meal tolerance test (MMT) without treatment intervention.	
Reporting group title	Acarbose
Reporting group description:	
Participants completed 1 week treatment with acarbose 50 mg at every meal together with CGM. After 1 week treatment, participants underwent a MMT.	
Reporting group title	Sitagliptin
Reporting group description:	
Participants completed 1 week treatment with sitagliptin 100 mg once daily together with CGM. After 1 week treatment, participants underwent a MMT.	
Reporting group title	Verapamil
Reporting group description:	
Participants completed 1 week treatment with verapamil 120 mg once daily together with CGM. After 1 week treatment, participants underwent a MMT.	
Reporting group title	Liraglutide
Reporting group description:	
Participants completed three weeks treatment with liraglutide, titrated from 0.6 to 1.2 mg once daily. During the last week of liraglutide treatment, participants also wore CGM. After the three weeks treatment period, participants underwent a MMT.	
Reporting group title	Pasireotide
Reporting group description:	
Participants received a 300 ug pasireotide injection 30 minutes prior to a MMT.	

Primary: Nadir blood glucose

End point title	Nadir blood glucose
End point description:	
Nadir blood glucose concentration during a mixed meal tolerance test with and without prior treatment intervention	
End point type	Primary
End point timeframe:	
End point was assessed during each study arm	

End point values	Baseline	Acarbose	Sitagliptin	Verapamil
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	10	11	11
Units: mmol/l				
arithmetic mean (standard error)	3.4 (± 0.2)	3.9 (± 0.2)	3.0 (± 0.2)	3.3 (± 0.2)

End point values	Liraglutide	Pasireotide		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	11		
Units: mmol/l				
arithmetic mean (standard error)	3.3 (± 0.2)	7.9 (± 0.4)		

Statistical analyses

Statistical analysis title	linear mixed models

Statistical analysis description:

The effects of treatment intervention was analysed using a linear mixed model analysis comparing treatment effect to baseline.

Comparison groups	Baseline v Acarbose v Sitagliptin v Verapamil v Liraglutide v Pasireotide
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Mixed models analysis

Secondary: Time in hypoglycemia

End point title	Time in hypoglycemia

End point description:

Time in hypoglycemia was assessed as minutes spend with blood glucose values <3.9 mmoL/l during a mixed meal tolerance test with and without treatment intervention.

End point type	Secondary

End point timeframe:

during each study arm

End point values	Baseline	Acarbose	Sitagliptin	Verapamil
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	10	11	11
Units: minutes				
arithmetic mean (standard error)	48 (± 12)	5 (± 3)	67 (± 10)	46 (± 11)

End point values	Liraglutide	Pasireotide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	11		
Units: minutes				
arithmetic mean (standard error)	55 (± 9)	0 (± 0)		

Statistical analyses

Statistical analysis title	mixed models analysis
Comparison groups	Baseline v Acarbose v Sitagliptin v Verapamil v Liraglutide v Pasireotide
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Mixed models analysis

Secondary: Peak blood glucose	
End point title	Peak blood glucose
End point description:	
Peak blood glucose level during a mixed meal tolerance test with and without treatment intervention	
End point type	Secondary
End point timeframe:	
During each study arm	

End point values	Baseline	Acarbose	Sitagliptin	Verapamil
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	10	11	11
Units: mmol/l				
arithmetic mean (standard error)	10 (± 0.4)	6.6 (± 0.6)	9.6 (± 0.5)	9.3 (± 0.4)

End point values	Liraglutide	Pasireotide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	11		
Units: mmol/l				
arithmetic mean (standard error)	9.4 (± 0.4)	14.5 (± 0.5)		

Statistical analyses

Statistical analysis title	linear mixed models
Comparison groups	Baseline v Acarbose v Sitagliptin v Verapamil v Liraglutide v Pasireotide
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.5
Method	Mixed models analysis

Secondary: Time in hyperglycemia

End point title	Time in hyperglycemia
End point description:	
Minutes spend with glucose levels >7.9 mmol/l during a mixed meal tolerance test with and without treatment intervention	
End point type	Secondary
End point timeframe:	
during each study arm	

End point values	Baseline	Acarbose	Sitagliptin	Verapamil
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	10	11	11
Units: minutes				
arithmetic mean (standard error)	29 (± 4)	5 (± 5)	22 (± 6)	29 (± 6)

End point values	Liraglutide	Pasireotide		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	11		
Units: minutes				
arithmetic mean (standard error)	29 (± 5)	159 (± 6)		

Statistical analyses

Statistical analysis title	linear mixed models
Comparison groups	Baseline v Acarbose v Sitagliptin v Verapamil v Liraglutide v Pasireotide

Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Mixed models analysis

Other pre-specified: Time in hypoglycemia (CGM)

End point title	Time in hypoglycemia (CGM)[1]

End point description:

Percentage of total recording time spend with glucose levels < 3.9 mmol/l during a 6-day continuous glucose monitorin with an without treatment intervention.

End point type	Other pre-specified

End point timeframe:

during each study arm except f (treatment with pasireotide)

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Continuous glucose monitoring (CGM) was not performed for the pasireotide arm, and thus this arm was not included in the statistics for all CGM outcomes.

End point values	Baseline	Acarbose	Sitagliptin	Verapamil
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	11	11
Units: percent				
arithmetic mean (standard error)	6.2 (± 1.3)	4.9 (± 1.1)	9.4 (± 2.5)	7.5 (± 3.1)

End point values	Liraglutide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: percent				
arithmetic mean (standard error)	9.4 (± 2.6)			

Statistical analyses

Statistical analysis title	linear mixed models
Comparison groups	Baseline v Acarbose v Sitagliptin v Verapamil v Liraglutide
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Mixed models analysis

Other pre-specified: Time in hyperglycemia (CGM)	
End point title	Time in hyperglycemia (CGM)[2]

End point description:

Percentage of total recording time spend with glucose levels < 3.9 mmol/l during a 6-day continuous glucose monitoring with an without treatment intervention.

End point type	Other pre-specified

End point timeframe:

during each study arm except f (treatment with pasireotide)

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Continuous glucose monitoring (CGM) was not performed for the pasireotide arm, and thus this arm was not included in the statistics for all CGM outcomes.

End point values	Baseline	Acarbose	Sitagliptin	Verapamil
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	11	11
Units: percentage time				
arithmetic mean (standard error)	8.8 (± 1.3)	4.2 (± 0.9)	4.8 (± 1.3)	10.4 (± 1.6)

End point values	Liraglutide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: percentage time				
arithmetic mean (standard error)	4.8 (± 1.0)			

Statistical analyses

Statistical analysis title	linear mixed models
Comparison groups	Baseline v Acarbose v Sitagliptin v Verapamil v Liraglutide
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Mixed models analysis

Other pre-specified: Hypoglycemic events (CGM)	
End point title	Hypoglycemic events (CGM)[3]

End point description:

Number of hypoglycemic events per day during a 6-day continuous glucose monitoring with an without treatment intervention.

End point type	Other pre-specified

End point timeframe:

during each study arm except f (treatment with pasireotide

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Continuous glucose monitoring (CGM) was not performed for the pasireotide arm, and thus this arm was not included in the statistics for all CGM outcomes.

End point values	Baseline	Acarbose	Sitagliptin	Verapamil
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	11	11
Units: events/day				
arithmetic mean (standard error)	1.5 (± 0.2)	1.4 (± 0.3)	1.9 (± 0.3)	1.4 (± 0.3)

End point values	Liraglutide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: events/day				
arithmetic mean (standard error)	1.8 (± 0.4)			

Statistical analyses

Statistical analysis title	linear mixed models
Comparison groups	Baseline v Acarbose v Sitagliptin v Verapamil v Liraglutide
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Mixed models analysis

Other pre-specified: Stanard deviation (CGM)

End point title	Stanard deviation (CGM)[4]

End point description:

Stanard deviation of the mean glucose value during a 6-day continuous glucose monitoring with an without treatment intervention.

End point type	Other pre-specified

End point timeframe:

during each study arm except f (treatment with pasireotide)

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Continuous glucose monitoring (CGM) was not performed for the pasireotide arm, and thus this arm was not included in the statistics for all CGM outcomes.

End point values	Baseline	Acarbose	Sitagliptin	Verapamil
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	11	11	11
Units: mmol/l				
arithmetic mean (standard error)	1.5 (± 0.1)	1.1 (± 0.1)	1.2 (± 0.1)	1.6 (± 0.1)

End point values	Liraglutide			
Subject group type	Reporting group			
Number of subjects analysed	11			
Units: mmol/l				
arithmetic mean (standard error)	1.2 (± 0.1)			

Statistical analyses

Statistical analysis title	linear mixed models
Comparison groups	Baseline v Acarbose v Sitagliptin v Verapamil v Liraglutide
Number of subjects included in analysis	55
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Mixed models analysis

Other pre-specified: iAUC for GLP-1

End point title	iAUC for GLP-1

End point description:

The baseline subtracted area under the curve for GLP-1 (glucagon-like peptide 1) during a mixed meal test with an without treatment intervention

End point type	Other pre-specified

End point timeframe:

During all study arms.

End point values	Baseline	Acarbose	Sitagliptin	Verapamil
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	10	11	11
Units: (nmol/L)/min				
arithmetic mean (standard error)	4829 (± 632)	5113 (± 750)	4996 (± 717)	4372 (± 694)

End point values	Liraglutide	Pasireotide		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	11		
Units: (nmol/L)/min				
arithmetic mean (standard error)	6295 (± 930)	1379 (± 290)		

Statistical analyses

Statistical analysis title	linear mixed models
Comparison groups	Baseline v Acarbose v Sitagliptin v Verapamil v Liraglutide v Pasireotide
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	Mixed models analysis

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Throughout each study arm (=treatment period)	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	10.0

Reporting groups	
Reporting group title	Acarbose
Reporting group description:	
Participants completed 1 week treatment with acarbose 50 mg at every meal together with CGM. After 1 week treatment, participants underwent a MMT.	
Reporting group title	Sitagliptin
Reporting group description:	
Participants completed 1 week treatment with sitagliptin 100 mg once daily together with CGM. After 1 week treatment, participants underwent a MMT.	
Reporting group title	Verapamil
Reporting group description:	
Participants completed 1 week treatment with verapamil 120 mg once daily together with CGM. After 1 week treatment, participants underwent a MMT.	
Reporting group title	Liraglutide
Reporting group description:	
Participants completed three weeks treatment with liraglutide, titrated from 0.6 to 1.2 mg once daily. During the last week of liraglutide treatment, participants also wore CGM. After the three weeks treatment period, participants underwent a MMT.	
Reporting group title	Pasireotide
Reporting group description:	
Participants received a 300 ug pasireotide injection 30 minutes prior to a MMT.	

Serious adverse events	Acarbose	Sitagliptin	Verapamil
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 11 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Serious adverse events	Liraglutide	Pasireotide	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	Acarbose	Sitagliptin	Verapamil
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 11 (81.82%)	4 / 11 (36.36%)	2 / 11 (18.18%)
Vascular disorders			
Palpitations	Additional description: s		
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 11 (0.00%)
occurrences (all)	0	9	0
Headache			
subjects affected / exposed	1 / 11 (9.09%)	2 / 11 (18.18%)	2 / 11 (18.18%)
occurrences (all)	9	18	18
General disorders and administration site conditions			
Tiredness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
nausea			
subjects affected / exposed	1 / 11 (9.09%)	4 / 11 (36.36%)	1 / 11 (9.09%)
occurrences (all)	9	36	9
Abdominal pain			
subjects affected / exposed	6 / 11 (54.55%)	0 / 11 (0.00%)	0 / 11 (0.00%)
occurrences (all)	55	0	0
Reduced appetite			
subjects affected / exposed	1 / 11 (9.09%)	3 / 11 (27.27%)	0 / 11 (0.00%)
occurrences (all)	9	27	0
Abdominal bloating			
subjects affected / exposed	6 / 11 (54.55%)	0 / 11 (0.00%)	0 / 11 (0.00%)
occurrences (all)	55	0	0
vomiting			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Diarrhoea			
subjects affected / exposed	2 / 11 (18.18%)	0 / 11 (0.00%)	0 / 11 (0.00%)
occurrences (all)	18	0	0
Skin and subcutaneous tissue disorders			
Allergic skin reaction			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Liraglutide	Pasireotide	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 11 (72.73%)	4 / 11 (36.36%)	
Vascular disorders			
Palpitations	Additional description: s		
subjects affected / exposed	1 / 11 (9.09%)	0 / 11 (0.00%)	
occurrences (all)	9	0	
Nervous system disorders			
dizziness			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	1 / 11 (9.09%)	0 / 11 (0.00%)	
occurrences (all)	9	0	
General disorders and administration site conditions			
Tiredness			
subjects affected / exposed	2 / 11 (18.18%)	4 / 11 (36.36%)	
occurrences (all)	18	36	
Gastrointestinal disorders			
nausea			
subjects affected / exposed	5 / 11 (45.45%)	1 / 11 (9.09%)	
occurrences (all)	45	9	
Abdominal pain			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Reduced appetite			
subjects affected / exposed	5 / 11 (45.45%)	0 / 11 (0.00%)	
occurrences (all)	45	0	
Abdominal bloating			

subjects affected / exposed	1 / 11 (9.09%)	0 / 11 (0.00%)	
occurrences (all)	9	0	
vomiting			
subjects affected / exposed	1 / 11 (9.09%)	1 / 11 (9.09%)	
occurrences (all)	9	9	
Diarrhoea			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Allergic skin reaction			
subjects affected / exposed	1 / 11 (9.09%)	0 / 11 (0.00%)	
occurrences (all)	9	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 October 2015	Change of inclusion and exclusion criteria.

Notes:

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.

It was not possible to recruit 16 participants (as decided by protocol) and thus only 11 particpants were included in the study. One participant did not complete the full study arm with acarbose treatment.

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/31144430