Clinical trial results:
The Impact of the Combination of the GLP-1 Analogue Liraglutide (Victoza®) and Laparoscopic Adjustable Gastric Banding (LAGB) on Diabetes Control

Summary

EudraCT number	2015-005402-11
Trial protocol	GB
Global end of trial date	31 March 2021

Results information

Result version number	v1 (current)
This version publication date	29 April 2026
First version publication date	29 April 2026
Summary attachment (see zip file)	GLIDE CSR (GLIDE CSR.pdf)

Trial information

Trial identification

Sponsor protocol code	GLIDE

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	U1111-1165-0989

Notes:

Sponsors

Sponsor organisation name	Guy's and St Thomas NHS Foundation Trust
Sponsor organisation address	Great Maze Pond, London, United Kingdom, SE1 9RT
Public contact	Dr Barbara McGowan, Guy's and St Thomas' NHS Foundation Trust, 44 02071881912, barbara.mcgowan@gstt.nhs.uk
Scientific contact	Dr Barbara McGowan, Guy's and St Thomas' NHS Foundation Trust, 44 02071881912, barbara.mcgowan@gstt.nhs.uk

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	31 March 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 March 2021
Global end of trial reached?	Yes
Global end of trial date	31 March 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine whether the addition of liraglutide to the gastric band results in improved glycaemic control

Protection of trial subjects:

Participants have the right to withdraw from the study at any time for any reason. The investigator has the right to terminate treatment with the study drug in the event of inter-current illness, AEs, SAEs, SUSARs, protocol violations, administrative reasons or other reasons such as:

- Inability to tolerate trial treatment.
- Non-adherence with trial procedures, at the discretion of the investigator
- Pregnancy
- Episodes of severe hypoglycaemia despite stoppage of hypoglycaemic medications
- Acute pancreatitis
- Deterioration in renal function (eGFR<30mL/min)

Patients who have had treatment with the study drug terminated early due to adverse events will be followed up clinically by members of the research team and referred on to an appropriate specialist where necessary.

Background therapy:

Obesity and Type 2 Diabetes Mellitus (T2DM) impose significant health burdens; bariatic surgery such as LAGB promotes weight loss and improves metabolic parameters [general knowledge implied].

Previous evidence supported GLP-1 receptor agonists for T2DM and obesity management through improved glycaemic control and weight loss.

LAGB is less favoured recently compared to other bariatric procedures (LSG or RYGB), especially in patients with T2DM, but remains used clinically. Combining GLP-1 receptor agonist therapy with LAGB may enhance metabolic outcomes, but this had not been evaluated in a randomized trial prior to GLIDE.

The GLIDE trial thus represents the first double-blind, placebo-controlled, randomized study testing liraglutide post-LAGB in patients with T2DM.

Evidence for comparator: -

Actual start date of recruitment	24 January 2017
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	United Kingdom: 27
Worldwide total number of subjects	27
EEA total number of subjects	27

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)	27
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details: -

Pre-assignment period milestones

Number of subjects started	66[1]
Number of subjects completed	27

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Not specified in CSR: 39

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: We do not count screening participants as enrolled

Period 1

Period 1 title	Treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Data analyst

Blinding implementation details:

This is a prospective double-blind randomised placebo-controlled trial. Following LAGB, patients will be randomised into receiving liraglutide or placebo. Randomisation will be carried out by a computer generated randomisation package. Patients will be assigned to either Liraglutide treatment or placebo using a minimisation algorithm.

For all analyses the statistician will be blind to the identity of the treatment given in the two arms until the last patient has completed their last visit a

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment arm

Arm description:

Liraglutide 1.8 mg one subcutaneous injection per day

Arm type	Experimental
Investigational medicinal product name	Liraglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Liraglutide 1.8 mg one subcutaneous injection per day

Arm title	Placebo

Arm description:

Placebo: Solution for subcutaneous injection in 3 mL pre-filled pen

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Solution for subcutaneous injection in 3 mL pre-filled pen

Number of subjects in period 1	Treatment arm	Placebo
Started	13	14
Completed	12	13
Not completed	1	1
Consent withdrawn by subject	1	-
Lost to follow-up	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Treatment arm
Reporting group description:	
Liraglutide 1.8 mg one subcutaneous injection per day	

Reporting group title	Placebo
Reporting group description:	
Placebo: Solution for subcutaneous injection in 3 mL pre-filled pen	

Reporting group values	Treatment arm	Placebo	Total
Number of subjects	13	14	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			
arithmetic mean	53.48	51.20	
standard deviation	± 8.31	± 8.59	-
Gender categorical Units: Subjects			
Female	10	11	21
Male	3	3	6

End points

End points reporting groups

Reporting group title	Treatment arm
Reporting group description:	
Liraglutide 1.8 mg one subcutaneous injection per day	

Reporting group title	Placebo
Reporting group description:	
Placebo: Solution for subcutaneous injection in 3 mL pre-filled pen	

Primary: 'the difference in change in HbA1C at 6 months from baseline (6 weeks post-surgery) between intervention and control groups

End point title	'the difference in change in HbA1C at 6 months from baseline (6 weeks post-surgery) between intervention and control groups[1]
End point description:	
In the CSR, it states no significant difference was seen at 6 month and the only numerical data was the HbA1c change from baseline at 12 months (which is the secondary endpoint).	
End point type	Primary
End point timeframe:	
Baseline (6 weeks post-surgery) to 6 months after	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Please see uploaded report

End point values	Treatment arm	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	14		
Units: mmol/mol				
median (full range (min-max))	0 (0 to 0)	0 (0 to 0)		

Statistical analyses

No statistical analyses for this end point

Secondary: The difference in change in HbA1C at 12 months from baseline (6 weeks post-surgery) between intervention and control groups

End point title	The difference in change in HbA1C at 12 months from baseline (6 weeks post-surgery) between intervention and control groups
End point description:	

End point type	Secondary
End point timeframe:	
Baseline (6 weeks post-surgery) to 12 months	

End point values	Treatment arm	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	14		
Units: mmol/mol				
median (full range (min-max))	8.0 (6.5 to 10.0)	-3.5 (-13.0 to 6.0)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From randomisation to 12 months after

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	Treatment arm

Reporting group description:

Liraglutide 1.8 mg one subcutaneous injection per day

Reporting group title	Placebo

Reporting group description: -

Serious adverse events	Treatment arm	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 13 (15.38%)	1 / 14 (7.14%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
Head injury			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain	Additional description: SAR		
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Treatment arm	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 13 (46.15%)	5 / 14 (35.71%)	
Injury, poisoning and procedural complications			
Pain of left upper quadrant			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Vascular disorders			
Dizziness			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Chest pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Surgical and medical procedures			
Gastric band related AEs			
subjects affected / exposed	6 / 13 (46.15%)	2 / 14 (14.29%)	
occurrences (all)	15	5	
Nervous system disorders			
Migraine			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
General disorders and administration site conditions			
Sweating			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Cramps (not GI)			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Irritable legs			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Itching			

subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	6 / 13 (46.15%)	0 / 14 (0.00%)	
occurrences (all)	6	0	
Diarrhoea			
subjects affected / exposed	1 / 13 (7.69%)	2 / 14 (14.29%)	
occurrences (all)	1	2	
Constipation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	2 / 13 (15.38%)	1 / 14 (7.14%)	
occurrences (all)	6	1	
Abdominal discomfort			
subjects affected / exposed	2 / 13 (15.38%)	1 / 14 (7.14%)	
occurrences (all)	2	1	
Gastro-oesophageal			
subjects affected / exposed	0 / 13 (0.00%)	2 / 14 (14.29%)	
occurrences (all)	0	2	
Loss of appetite			
subjects affected / exposed	2 / 13 (15.38%)	0 / 14 (0.00%)	
occurrences (all)	2	0	
Bloating			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Dry mouth			
subjects affected / exposed	1 / 13 (7.69%)	0 / 14 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 14 (7.14%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			

Sciatic pain subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 14 (0.00%) 0	
Infections and infestations Thrush subjects affected / exposed occurrences (all) Urinary tract infection subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1 1 / 13 (7.69%) 1	1 / 14 (7.14%) 1 0 / 14 (0.00%) 0	
Metabolism and nutrition disorders Numbness/cold to extremities subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	0 / 14 (0.00%) 0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 December 2017	SA01 protocol v3.0
07 March 2019	SA 02 protocol v4 with RSI update

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported