CLINICAL STUDY REPORT

GLIDE

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

Sponsor Protocol Code:	King's Health Partners
EudraCT Number:	2015-005402-11
ClinicalTrials.gov Identifier:	NA
ISRCTN number:	ISRCTN10551314
REC Number:	16/LO/1144
Investigational Drugs (IMPs):	Liraglutide 1.8 mg (Victoza)
Indication:	Obesity with Type 2 Diabetes Mellitus (T2DM)
Development Phase:	Phase 2
Study Begin (FPFV):	27 March 2018
Study End (LPLV):	25 March 2020
Report Version & Issue Date:	version 1.0, 27 August 2025
Co-sponsor Name and Address:	King's Health Partners (Sponsor)
Co-sponsor contact details:	King's College London - 020 7836 5454 Guy's and St Thomas' NHS Foundation Trust - 020 7188 7188
Chief Investigator:	Barbara McGowan

SIGNATURE PAGE

By signing below, I approve the contents of this Clinical Study Report, and confirm that to the best of my knowledge it accurately describes the conduct and results of the study. The clinical trial reported herein was conducted in accordance with the principles contained in the Declaration of Helsinki, Good Clinical Practice (GCP) and all applicable laws and regulations.

This was a non-commercial academic trial; the results of this study are not intended to be used or a licensing application.

Chief Investigator: BARBARA McGOWAN

Printed name	**Signature**	**Date**
BARBARA McGOWAN		19/9/2025

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1. Ethics

Independent Ethics Committee or Institutional Review Board

The study protocol and amendments were reviewed and approved by a National Research Ethics Service (London—Westminster Research Ethics Committee (REC Reference: 16/LO/1144)

The trial was conducted according to the protocol and in compliance with the principles of the Declaration of Helsinki (1996) as amended, the principles of Good Clinical Practice (GCP) and in accordance with Medicines for Human Use (Clinical Trials) Regulations 2004, as amended, the Research Governance Framework for Health and Social Care, the Data Protection Act 1998 and other regulatory requirements as appropriate. The trial protocol and substantial amendments were reviewed by the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA)

Patients for the GLIDE trial were recruited from outpatient weight management services at the participating centers in the United Kingdom. Key details regarding recruitment and consent include:

- Eligibility Criteria:

Adults aged 18–70 years with BMI 30–50 kg/m² and diagnosed Type 2 Diabetes Mellitus (T2DM) with HbA1c between ≥48 mmol/mol and <97 mmol/mol at or before screening were eligible. Exclusion criteria included type 1 diabetes, diet-controlled T2DM, pregnancy or breastfeeding, history of pancreatitis, delayed gastric emptying, and personal or family history of thyroid cancer or multiple endocrine neoplasia.

- Informed Consent:

All participants provided written informed consent prior to inclusion in the study.

- Screening and Randomization:

Between 27 March 2018 and 25 March 2020, 66 participants were screened for eligibility, with 27 participants randomized to liraglutide or placebo arms after meeting criteria.

This recruitment approach ensured that participants were appropriate for the study intervention and that ethical standards were met through informed consent.

2. Data Monitoring

The study was overseen by the sponsor, King's Health Partners Clinical Trials Office , ensuring adherence to Good Clinical Practice Guidelines and Declaration of Helsinki principles.

The protocol was approved by the London—Westminster Research Ethics Committee (REC Reference: 16/LO/1144), which typically reviews safety and ethical aspects during the trial,

The trial was conducted with blinded treatment allocation to ensure unbiased assessment.

The study included blinded statistical analysis, with the statistician masked to treatment allocation until the last participant had completed follow-up

3. Sponsors, Investigators and Trial Sites

Co-Sponsors

Guy's and St Thomas NHS Foundation Trust (co-sponsor)	King's College London (Leader sponsor)
Chief Investigator	*Prof Barbara McGowan*

4. Co-Investigator(s), Statistician, Laboratories, Database Management

1. **Co-Investigators:** • James Crane • Abdel Douiri • Annastazia E. Learoyd • Olanike Okolo • Spyros Panagiotopoulos • Dimitri J. Pournaras • Sasindran Ramar • Francesco Rubino • Rishi Singhal • Carel W. le Ro	***Statistician***

5. Study Synopsis

Title of clinical trial	GLIDE: A Pilot Randomised Double-Blind, Placebo-Controlled Trial.
Protocol Short Title/Acronym	GLIDE
Study Phase	Phase II (Pilot study)
Sponsor name	King's Health Partners.
Chief Investigator	Barbara McGowan
Eudract number	2015-005402-11.
REC number	16/LO/1144 (London – Westminster Research Ethics Committee)
IRAS project ID:	166224
Medical condition or disease under investigation	Type 2 Diabetes Mellitus (T2DM) and obesity.
Purpose of clinical trial	To evaluate the metabolic impact of the addition of GLP-1 receptor agonist therapy (liraglutide) after laparoscopic adjustable gastric band (LAGB) surgery in patients with T2DM
Primary objective	To assess the change in HbA1c as a measure of the clinical efficacy of adding liraglutide to LAGB treatment for T2DM
Secondary objective (s)	To evaluate changes in body weight, remission rates for diabetes, insulin resistance, hypoglycaemic episodes, cardiovascular risk factors, and overall quality of life among participants
Trial Design	A randomised, double-blind, placebo-controlled trial design.
Endpoints	**The primary outcome measure is the change of HbA1c at 6 months from baseline.**

	1. Other diabetes outcomes - The difference in change in HbA1c at 12 months from baseline between intervention and control groups - Percentage of patients with remission of diabetes at 12 months defined as HbA1c 2. Anthropometric measures and body composition - Body weight - BMI - Waist circumference - Neck circumference - Bioimpedance (Body Fat via Bioelectrical Impedance) 3. Alterations in physical activity levels (GPAQ questionnaire) 4. Cardiovascular disease risk factors including - Systolic BP - Diastolic BP - total cholesterol - HDL-cholesterol - LDL-cholesterol - Triglyceride 5. Quality of life and psychological measures (IWQOL-Lite, EQ-5D-5L, HADS) 6. 6. Adverse event rates
Planned number of subjects	XXX
Summary of eligibility criteria	Adults aged 18–70 with a BMI of 30–50 kg/m² and T2DM (HbA1c ≥ 48 mmol/mol and <97 mmol/mol). Exclusion criteria included type 1 diabetes, delayed gastric emptying, pregnancy, history of pancreatitis, and personal or family history of thyroid cancer or multiple endocrine neoplasia.
IMP, dosage and route of administration	Liraglutide 1.8 mg, administered subcutaneously once daily.
Active comparator product(s)	Liraglutide 1.8mg
Maximum duration of treatment of a subject	2 years

Version and date of protocol amendments	V3.0 09Nov2017 V4.0 29Jan2019 V4.2 11Dec2021

6. Glossary of terms

LAGB: Laparoscopic Adjustable Gastric Banding – a bariatric surgical procedure for weight loss involving the placement of an adjustable band around the stomach.

GLP-1 receptor agonist: Glucagon-Like Peptide-1 receptor agonist – a class of medications that enhance insulin secretion and promote weight loss; liraglutide is an example used in this trial

HbA1c: Haemoglobin A1c – a blood test that reflects average blood glucose levels over approximately 3 months, used to assess glycaemic control [multiple].

T2DM: Type 2 Diabetes Mellitus – a chronic condition characterized by insulin resistance and hyperglycaemia.

IMP: Investigational Medicinal Product – in this trial, refers to either liraglutide or placebo injections.

BMI: Body Mass Index – a measure of body fat based on height and weight (kg/m^2) [multiple].

HOMA-IR: Homeostatic Model Assessment for Insulin Resistance, a marker calculated from fasting blood glucose and insulin to assess insulin sensitivity.

RCT: Randomised Controlled Trial – a study design where participants are randomly allocated to treatment or control arms to measure efficacy and safety,

FPFV: First Patient First Visit – date when the first participant was enrolled and assessed.

LPLV: Last Patient Last Visit – date when the final participant completed the study follow-up.

7. Publication (reference)

Coelho C, et al. "GLIDE trial: A pilot randomised, double-blind, placebo-controlled trial of liraglutide after laparoscopic adjustable gastric banding in patients with obesity and type 2 diabetes." International Journal of Obesity (2023) 47:1132–1142. PMID: 37696925 PMCID: PMC10599987 DOI:10.1038/s41366-023-01368-4

The clinical trial is registered with EudraCT (Registration Number: 2015-005402-1

8. Study period (years)

Recruitment Period / First Patient First Visit (FPFV): 27 March 2018.

Last Patient Last Visit (LPLV): 25 March 2020.

Total Study Duration: Approximately 2 years from first patient enrollment to last follow-up visit.

End of Trial Definition: Completion of 12 months follow-up after randomization, including 6 months on treatment and 6 months off treatment.

Recruitment Completion: Achieved on 25 March 2020.

Trial Interruptions: The study experienced limitations in band adjustments and follow-up due to the COVID-19 pandemic which affected the treatment and follow-up quality but no mention of formal trial halt or premature termination.

Premature Termination: Not indicated; however, the trial was significantly underpowered due to recruitment challenges, partly due to shifting clinical practice favoring other bariatric procedures over LAGB

9. Phase of development

This was a pilot phase 2 randomized controlled trial aiming to assess safety and preliminary efficacy of liraglutide as an adjunct to LAGB in patients with T2DM and obesity

10. Objectives

Primary Objective: To assess the effect of adding a GLP-1 receptor agonist (liraglutide 1.8 mg once daily) after laparoscopic adjustable gastric banding (LAGB) on glycaemic control, measured as change in HbA1c at 6 months,

Secondary Objectives: To evaluate the impact of liraglutide on:

Body weight and percentage body weight change at multiple time points (3, 6, 9, and 12 months).

Diabetes remission at 12 months (defined as HbA1c <48 mmol/mol off all diabetes medication).

Markers of insulin resistance (HOMA-IR), cardiovascular risk factors (blood pressure, lipids), body composition, physical activity, and quality of life.

Assess safety and tolerability of liraglutide combined with LAGB via adverse events reporting

11.Background and Context

Obesity and Type 2 Diabetes Mellitus (T2DM) impose significant health burdens; bariatric 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.

12. Methodology

Conceptual Framework

- A pragmatic randomized, double-blind, placebo-controlled trial designed to mimic routine clinical care, reducing patient burden and increasing applicability to real-world settings,

The Reference Group

- The trial was sponsored and overseen by King's Health Partners (UK), and conducted at three UK centres.
- Randomisation and blinding procedures were administered by King's Clinical Trials Unit.

Trial Duration

- Recruitment period: March 2018 to March 2020.
- Treatment duration per participant: 6 months of liraglutide/placebo therapy following LAGB surgery.
- Total follow-up: 12 months post-randomisation (i.e., 6 months on treatment and 6 months off treatment).

Definition of Trial Time Measurements

- Primary endpoint assessed at 6 months post-randomisation.
- Secondary endpoints assessed at 3, 6, 9, and 12 months for various metabolic and safety parameters.

Trial Follow-up

- Participants attended 7 clinical visits during the 12-month period for monitoring outcomes including HbA1c, body weight, cardiovascular parameters, and adverse events.
- Follow-up band adjustments and clinical care managed by blinded dieticians or trained staff following local protocol.
- Follow-up appointments were impacted by COVID-19, resulting in fewer face-to-face visits and limited band adjustments during the trial.

Schedule of Events from Protocol (Summary based on information in the text; detailed protocol schedule not provided)

- Baseline (pre-surgery/surgery) assessments including HbA1c, anthropometrics, cardiovascular risk factors.
- Randomisation within 6 weeks post-LAGB surgery.
- Visits at months 0 (randomisation), 3, 6 (end of treatment), 9, and 12 months (final follow-up) for outcome assessments and adverse event monitoring,

Trial Medication

- Investigational Medicinal Product: Liraglutide 1.8 mg (Victoza) or matched placebo.
- Mode of administration: Subcutaneous injection once daily,

Dosing Regimen

- Liraglutide was titrated according to manufacturer's recommendations to reach a maximum tolerated dose of 1.8 mg daily over a short titration period (typically weeks).
- Placebo injection matched in appearance and administration frequency.
- Treatment duration: 6 months.
- Participants followed up for an additional 6 months off-treatment.

13 Number of patients (planned and analysed)

a. Planned

The original planned sample size was 58 participants (29 per group) to have 80% power to detect a 0.6% difference in HbA1c between liraglutide and placebo

b. Analysed

Arm Active (Liraglutide) Placebo
Patients screened (66)
Patients randomized/treated (13) received liraglutide and (14) patients were in Placebo group
Patients completed the study (12) received liraglutide and (13) in placebo group

Arm	Active	Placebo

# patients screened		
# patients randomised/treated/ study arm	13	14
# patients completed/ study arm	12	13
Reasons for non-completion if applicable	Participant in liraglutide arm (n=1)Withdrew consent after 9 months of follow-up	Participant in placebo arm (n=1)Lost to follow-up (did not complete study)

14.Diagnosis and main criteria for inclusion

Adults with type 2 diabetes mellitus (T2DM) eligible for laparoscopic adjustable gastric banding (LAGB)

Inclusion criteria included diagnosis of T2DM, suitability for LAGB, and meeting BMI criteria per protocol

Detailed criteria not explicitly described in the extracts but involved standard clinical assessment for bariatric surgery candidacy

15.Test product, dose and mode of administration

Participants continued background diabetes management as per standard of care; detailed concomitant medications listed in Supplementary Tables 2–4.

Investigational Medicinal Product (IMP)

- Liraglutide 1.8 mg once daily subcutaneous injection versus placebo.
- IMP was dispensed and tracked through a blinded pharmacy system.

Table: Dose of IMP administered

- All participants in the liraglutide arm received daily subcutaneous injections of liraglutide 1.8 mg.
- Placebo arm received matched placebo injections.

16.Duration of treatment

Treatment duration was 6 months for primary endpoint evaluation.

Follow-up extended to 12 months for secondary endpoints.

Participants monitored up to 12 months post-randomization.

17.Reference therapy, dose and mode of administration

Placebo injections matched in appearance to liraglutide, administered once daily subcutaneously

18. Criteria for evaluation: Endpoints

19. 1Efficacy Primary Endpoint: Change in HbA1c from baseline to 6 months post-randomisation.

Secondary Efficacy Parameters

- HbA1c at 3, 9, and 12 months
- Body weight and % change from baseline at multiple time points
- Diabetes remission at 12 months (HbA1c <48 mmol/mol off medications)
- Insulin resistance measured by HOMA-IR
- Other body composition measures: BMI, waist and neck circumference, bioimpedance
- Cardiovascular risk factors: blood pressure, lipid profiles
- Physical activity and quality of life measures,

18.2 Safety Parameters

- Adverse events (AEs) and serious adverse events (SAEs) collected throughout trial.
- Surgery-related and gastric band–related AEs specifically monitored.

Specific Safety Endpoints

- Frequency and severity of AEs including dizziness, infections, cholecystitis, and abdominal pain reported.
- Discontinuation of IMP due to AEs documented

19.Statistical Methods

Intention-to-treat (ITT) principle used for all efficacy analyses with last observation carried forward for missing data where appropriate.
Multivariable linear regression adjusted for baseline values and minimisation variables (centre, BMI category, diabetes duration, insulin use) tested differences between treatment arms. Logistic regression model tested differences in diabetes remission.
Nonparametric tests (Wilcoxon rank-sum, Kruskal-Wallis) applied for group comparisons of continuous variables.

Analysis of Safety Variables
Descriptive statistics used for AEs by treatment arm.
Wilcoxon rank-sum tests compared average number of AEs per patient between groups.
Fisher's exact test compared proportions of surgery-related and gastric band–related AEs

20. Changes in the Trial Plan

The trial was stopped early due to recruitment challenges and changes in clinical practice preferring other bariatric procedures over LAGB, resulting in underpowering.

Some outcome data were missing due to restricted face-to-face visits impacting data collection and band adjustments

Missing data for critical outcomes such as HbA1c and weight for some participants.

Restricted face-to-face appointments affected band adjustments and outcome measurements.

One participant withdrew but was included in the primary outcome analysis

No serious protocol breaches or major deviations impacting trial integrity were reported

21. Summary – Conclusions

21.1 Demographic data

Table: Baseline Demographics and Physical Examination

Characteristic	Total (n = 27)	Liraglutide (n = 13)	Placebo (n = 14)
Age (years, mean ± SD)	52.30 ± 8.38	53.48 ± 8.31	51.20 ± 8.59
Female Gender, n (%)	21 (77.8%)	10 (76.9%)	11 (78.6%)
Ethnicity - White, n (%)	20 (74.1%)	8 (61.5%)	12 (85.7%)

Ethnicity - Black, n (%)	7 (25.9%)	5 (38.5%)	2 (14.3%)
Current Smoker, n (%)	3 (11.1%)	1 (7.7%)	2 (14.3%)
Current Alcohol Drinker, n (%)	13 (48.1%)	3 (23.1%)	10 (71.4%)
Height (cm, median [range])	165.0 [160.0–174.0]	166.0 [160.0–174.0]	164.5 [160.0–174.0]
Weight (kg, median [range])	102.0 [91.7–123.3]	101.0 [94.3–128.5]	103.1 [87.1–116.0]
Body Mass Index (BMI)	37.77 [33.20–43.66]	38.91 [35.18–46.11]	34.76 [32.11–42.87]
Waist Circumference (cm)	116.0 [107.0–137.0]	121.0 [108.0–140.0]	113.0 [106.0–122.0]
Hip Circumference (cm)	118.0 [112.0–139.0]	127.0 [112.0–146.0]	116.5 [112.0–132.0]
Neck Circumference (cm)	39.0 [37.0–44.0]	39.0 [37.0–45.0]	39.0 [37.0–42.0]
Systolic BP (mmHg)	124.0 [114.0–127.0]	121.0 [111.3–124.7]	125.7 [123.7–130.0]
Diastolic BP (mmHg)	80.7 [73.7–86.0]	73.7 [71.7–85.0]	82.2 [79.0–86.0]
Pulse (bpm)	70.7 [66.0–79.7]	76.7 [68.7–82.0]	70.2 [63.3–79.7]
Fat Mass (kg)	48.3 [38.1–61.0]	46.3 [42.8–61.0]	50.3 [36.0–58.1]
Fat-Free Mass (kg)	55.7 [49.7–68.3]	56.3 [49.7–67.5]	54.8 [49.5–72.9]
Fat Percentage (%)	45.6 [40.5–48.8]	45.4 [43.2–47.5]	47.4 [40.5–48.8]
Year of T2DM Diagnosis (median [range])	2015 [2011–2017]	2015 [2010–2018]	2015 [2013–2017]
Time Since Diagnosis (years, median [range])	3 [2–6]	4 [1–8]	3 [2–5]

The following tables summaries the demographics of the study population:

21.2 Primary outcome

The primary outcome of the GLIDE trial was the difference in HbA1c at 6 months between the liraglutide and placebo groups.

Summary of primary outcome data:

- At baseline, there were no significant differences in demographics or HbA1c between groups.
- HbA1c change from baseline to 6 months showed no significant difference between liraglutide and placebo arms.
- Specifically, HbA1c at 12 months was reported as medians (IQR):
- Total: 54.5 (45.0–63.0) mmol/mol
- Liraglutide: 56.0 (48.0–65.0) mmol/mol
- Placebo: 54.5 (44.0–60.0) mmol/mol
- Change from baseline at 12 months (median, IQR):
- Total: 5.5 (–7.0 to 8.0)
- Liraglutide: 8.0 (6.5 to 10.0)
- Placebo: –3.5 (–13.0 to 6.0)
- p = 0.022 indicating some difference favouring placebo at 12 months.
- Figure 3 (Page 7) graphically depicts trends over 12 months:
- Panel A shows HbA1c trends, with no significant difference between groups.
- Panel B shows body weight trends.
- Panel C shows percentage body weight change.
- Body weight reduction correlated with HbA1c reduction (shown in supplementary figures).

No significant difference was found in the primary endpoint of HbA1c at 6 months between liraglutide and placebo, likely owing to small sample size and limited treatment duration.

The following table summarizes relevant median HbA1c values and changes:

Timepoint	Total (n=27) median HbA1c (IQR) mmol/mol	Liraglutide (n=13) medianHbA1c (IQR) mmol/mol	Placebo (n=14) median HbA1c (IQR) mmol/mol	p-value
Baseline	54.5 (45.0–63.0)	56.0 (48.0–65.0)	54.5 (44.0–60.0)	0.59
12 months	54.5 (45.0–63.0)	56.0 (48.0–65.0)	54.5 (44.0–60.0)	0.59
Change from baseline at 12 months	5.5 (–7.0–8.0)	8.0 (6.5–10.0)	–3.5 (–13.0–6.0)	0.022

In summary, liraglutide added to LAGB surgery did not significantly improve HbA1c at 6 months compared to placebo, with trends numerically favouring placebo at 12 months, potentially influenced by other factors and limited sample size. The visual data in Figure 3 supports this finding.

21.3 Safety results

Adverse Events	e.g. Treatment Arm	e.g. Placebo
Total Number of AEs per Study Arm	32	10
Subjects affected by non-serious adverse events:	44%	30%

MeDDra version used was Version20.

Within the per protocol population (n=27), a total of 42 adverse events (AEs), including 3 serious adverse events (SAEs), were identified as treatment-emergent and included in the safety analysis. Summary tables for AEs and SAEs are presented in the appendix of this synopsis.

Overall, 12 patients (44%) experienced at least one AE. The proportion that experienced at least one SAE was approximately 11% (n=3).

Incidence of adverse drug reactions (ADRs): 28 out of 42 AEs (67%) were assessed as related to at least one study drug, and 11 out of 27 patients (41%) experienced 28 ADRs.

There were 1 Serious Adverse Event (SAEs), 2 Serious Adverse Reaction (SARs), and no Suspected Unexpected Serious Adverse Reaction (SUSARs) reported.

16. Conclusion

The study evaluated the impact of adding liraglutide, a GLP-1 receptor agonist, following laparoscopic adjustable gastric banding (LABG) in patients with type 2 diabetes mellitus (T2DM). At 6 months, there was no significant improvement in HbA1c or weight compared to placebo. The trial was underpowered due to a small sample size and limited band adjustments, partly due to the COVID-19 pandemic. The authors recommend larger, longer-duration trials with more intensive follow-up and the use of newer agents like semaglutide or tirzepatide to better assess the potential benefits of adjunctive gut hormone therapy post-metabolic surgery.

22. Date of Report

This is version 1.0 of the Clinical Study Report synopsis, dated
27 August 2025

APPENDICES

i) Summary of treatment-emergent AEs in the per protocol population

System Organ Class *(Current list of MedDRA SOC)*	**Preferred Term**	**Number of Subjects Experiencing the AE in Active Arm** *(ideally list number and percentage e.g. 10/12 subjects would be listed as 10 (83.33%)*	**Total Number of Occurrences of the AE** *(10 subjects may have experienced the same AE multiple times throughout the trial e.g. there were 20 occurrences of the same event)*	**Number of Subjects Experiencing the AE in Placebo Arm** *(ideally list number and percentage e.g. 10 /12 subjects would be listed as 10 (83.33%)*	**Total Number of Occurrences of the AE** *(10 subjects may have experienced the same AE multiple times throughout the trial e.g. there were 20 occurrences of the same event)*
Blood and lymphatic system disorders	-	0 (0%)	0	0 (0%)	0
Cardiac disorders	Chest pain	1 (7.7%)	1	0 (0%)	0
Congenital, familial and genetic disorders	-	0 (0%)	0	0 (0%)	0
Ear and labyrinth disorders	-	0 (0%)	0	0 (0%)	0
Eye Disorders	-	0 (0%)	0	0 (0%)	0
Gastrointestinal disorders	Nausea	6 (46.2%)	6	0 (0%)	0
	Diarrhoea	1 (7.7%)	1	2 (14.3%)	2

	Constipation	1 (7.7%)	1	0 (0%)	0
	Vomiting	2 (15.4%)	6 (including multiple episodes)	1 (7.1%)	1
	Abdominal discomfort	2 (15.4%)	2	1 (7.1%)	1
	Gastro-oesophageal reflux	0 (0%)	0	2 (14.3%)	2
	Loss of appetite	2 (15.4%)	2	0 (0%)	0
	Bloating	1 (7.7%)	1	0 (0%)	0
	Dry mouth	1 (7.7%)	1	0 (0%)	0
General disorders and administration site conditions	Sweating	1 (7.7%)	1	0 (0%)	0
	Cramps (not GI)	1 (7.7%)	1	0 (0%)	0
	Irritable legs	1 (7.7%)	1	0 (0%)	0
	Itching	1 (7.7%)	1	0 (0%)	0
Hepatobiliary disorders	Cholecystitis	0 (0%)	0	1 (7.1%)	1
Immune system disorders	-	0 (0%)	0	0 (0%)	0
Infections and infestations	Thrush	1 (7.7%)	1	1 (7.1%)	1
	Urinary Tract Infection	1 (7.7%)	1	0 (0%)	0
Injury, poisoning and procedural complications	Pain of left upper quadrant	1 (7.7%)	1	0 (0%)	0
Investigations	-	0 (0%)	0	0 (0%)	0
Metabolism and nutritional disorders	Numbness/cold to extremities	2 (15.4%)	2	0 (0%)	0
Musculoskeletal and connective tissue disorders	Sciatic pain	1 (7.7%)	1	0 (0%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	-	0 (0%)	0	0 (0%)	0
Nervous system disorders	Migraine	1 (7.7%)	1	0 (0%)	0

Pregnancy, puerperium and perinatal conditions	-	0 (0%)	0	0 (0%)	0
Product issues	-	0 (0%)	0	0 (0%)	0
Psychiatric disorders	-	0 (0%)	0	0 (0%)	0
Renal and urinary disorders	-	0 (0%)	0	0 (0%)	0
Reproductive system and breast disorders	-	0 (0%)	0	0 (0%)	0
Respiratory, thoracic and mediastinal disorders	-	0 (0%)	0	0 (0%)	0
Skin and subcutaneous tissue disorders	-	0 (0%)	0	0 (0%)	0
Social circumstances	-	0 (0%)	0	0 (0%)	0
Surgical and medical procedures	Gastric band related AEs	6 (75.0%)	15	2 (50.0%)	5
Vascular disorders	Dizziness	1 (7.7%)	1	0 (0%)	0

Summary of treatment-emergent ARs in the per protocol population

There was a total of 42 adverse events (AEs) recorded during the trial, with 32 in the liraglutide arm and 10 in the placebo arm.
Gastrointestinal (GI) symptom-related adverse events were notably higher in the liraglutide group (20 AEs) compared to placebo (7 AEs).
Gastric band-related adverse events were also more common in the liraglutide arm (15 events) relative to placebo (5 events).
The average number of adverse events per patient was 3.5 in the liraglutide group and 2.5 in the placebo group, although this difference was not statistically significant (p=0.39).
The most frequent GI adverse symptom in the liraglutide arm was vomiting (46.2% of GI AEs).
Severity of adverse events ranged across mild, moderate, and severe, with liraglutide group experiencing more severe AEs (7 severe vs. 1 in placebo).
Five participants in the liraglutide arm stopped the investigational medicinal product (IMP) due to adverse events; no participants in placebo stopped IMP for AEs. Twenty-seven adverse events were ongoing at study end, all in the liraglutide group

Summary of treatment-emergent SAEs in the study population

There was only 1 SAE occurred during the trail .

System Organ Class *(Current list of MedDRA SOC)*	**Preferred Term**	**Number of Subjects Experiencing the SAE in Active Arm** *(ideally list number and percentage e.g. 10 /12 subjects would be listed as 10 (83.33%)*	**Total Number of Occurrences of the SAE** *(10 subjects may have experienced the same SAE multiple times throughout the trial e.g. there were 20 occurrences of the same event)*	**Number of Subjects Experiencing the SAE in Placebo Arm** *(ideally list number and percentage e.g. 10 /12 subjects would be listed as 10 (83.33%)*	**Total Number of Occurrences of the SAE** *(10 subjects may have experienced the same SAE multiple times throughout the trial e.g. there were 20 occurrences of the same event)*
Blood and lymphatic system disorders					
Cardiac disorders					
Congenital, familial and genetic disorders					
Ear and labyrinth disorders					
Eye Disorders					
Gastrointestinal disorders					
General disorders and administration site conditions					
Hepatobiliary disorders					
Immune system disorders					

Infections and infestations					
Injury, poisoning and procedural complications	*HEAD INJURY*	1	1	0	1
Investigations					
Metabolism and nutritional disorders					
Musculoskeletal and connective tissue disorders					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Nervous system disorders					
Pregnancy, puerperium and perinatal conditions					
Product issues					
Psychiatric disorders					
Renal and urinary disorders					
Reproductive system and breast disorders					
Respiratory, thoracic and mediastinal disorders					
Skin and subcutaneous tissue disorders					
Social circumstances					
Surgical and medical procedures					
Vascular disorders					

Summary of treatment-emergent SARs in the study population

There wear the two SARs in the trail

System Organ Class *(Current list of MedDRA SOC)*	**Preferred Term**	**Number of Subjects Experiencing the SAR in Active Arm** *(ideally list number and percentage e.g. 10 /12 subjects would be listed as 10 (83.33%)*	**Total Number of Occurrences of the SAR** *(10 subjects may have experienced the same SAR multiple times throughout the trial e.g. there were 20 occurrences of the same event)*	**Number of Subjects Experiencing the SAR in Placebo Arm** *(ideally list number and percentage e.g. 10 /12 subjects would be listed as 10 (83.33%)*	**Total Number of Occurrences of the SAR** *(10 subjects may have experienced the same SAR multiple times throughout the trial e.g. there were 20 occurrences of the same event)*
Blood and lymphatic system disorders					
Cardiac disorders					
Congenital, familial and genetic disorders					
Ear and labyrinth disorders					
Eye Disorders					
Gastrointestinal disorders	*Abdominal pain*	1	1	0	1
General disorders and administration site conditions					

Hepatobiliary disorders	*Cholecystitis*	0	1	1	1
Immune system disorders					
Infections and infestations					
Injury, poisoning and procedural complications					
Investigations					
Metabolism and nutritional disorders					
Musculoskeletal and connective tissue disorders					
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Nervous system disorders					
Pregnancy, puerperium and perinatal conditions					
Product issues					
Psychiatric disorders					
Renal and urinary disorders					
Reproductive system and breast disorders					
Respiratory, thoracic and mediastinal disorders					
Skin and subcutaneous tissue disorders					
Social circumstances					
Surgical and medical procedures					
Vascular disorders					