ISRCTN10551314 https://doi.org/10.1186/ISRCTN10551314

# GLIDE: Gastric band and Liraglutide Intervention in Diabetes Evolution

**Submission date**
21/11/2016

**Recruitment status**
No longer recruiting

**Registration date**
28/11/2016

**Overall study status**
Completed

**Last Edited**
10/05/2021

**Condition category**
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Type 2 diabetes mellitus (T2DM) is a growing problem worldwide. People with T2DM have difficulty controlling their blood sugar (glucose) as they do not produce enough insulin to function properly (insulin deficiency), or that the body's cells don't react to insulin as they should do (insulin resistance). One of the most common causes of T2DM is obesity. Although weight loss can help significantly in the treatment of T2DM, the treatments used for diabetics can make it harder for a person to lose weight. Bariatric surgery (weight loss surgery) is a drastic measure used to help people who are dangerously overweight. Laparoscopic adjustable gastric band (LAGB) is a surgical weight-loss (bariatric) procedure increasingly used in the UK. It involves surgically placing a band around the top portion of the stomach to lower the capacity of the stomach, helping the person to lose weight. Although other bariatric surgery procedures produce more predictable weight reduction and diabetes resolution, LAGB is much easier to perform, has a significantly lower death rate and is cheaper. It is therefore important to explore mechanisms to improve LAGB success. Liraglutide is a drug which is similar to a natural gut hormone produced by the body which stimulates post-meal insulin secretion and reduces appetite. The aim of this study is to find out whether a combination of liraglutide and LAGB is likely to offer extremely obese patients with diabetes the opportunity of achieving significant weight loss and diabetes resolution with minimal surgical risk.

Who can participate?
Obese adults with T2DM.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group undergo treatment with liraglutide in addition to their usual treatment six weeks after their gastric band surgery. Those in the second group undergo treatment with a placebo (dummy medicine) in addition to their usual treatment six weeks after their gastric band surgery. In both groups, the medication is injected once a day using a pen-injector. Specific instructions regarding how to use the pen-injector and the drug regime are provided. Patients receive treatment for 6 months and continue to be followed up for another 6 months after treatment has finished. Participants are

required to attend six hospital visits and take part in one telephone call during the trial. The visits include the collection of blood samples, completion of questionnaires and other information required for the trial.

What are the possible benefits and risks of participating?
Participants will have frequent contact with members of the research team so any problems can be quickly identified and addressed. Test results and explanations will be provided so patients will have more information about their health, this can help educate and encourage patients to make changes to their lifestyle and diabetes care. Participating in this research may lead to changes in the future that will be beneficial to others undergoing gastric band surgery. From visit two, travel expenses will be available up to a maximum of £10 per visit. There are some risks associated with participating in the study. Blood samples will need to be taken as part of the trial and there is a small chance of fainting, bruising, bleeding, swelling or infection where the needle is inserted. The risk will be minimised by having qualified and experienced staff members perform this procedure. Where possible, research blood samples will be taken at the same time as routine care blood samples so patients will not be exposed to additional needles for the research. There is also a time commitment in participating, however, appointments and tests will be scheduled alongside routine visits if possible. If participants are randomly allocated to take Liraglutide, there are some side effects associated with this medication, which will be explained prior to agreeing to take part.

Where is the study run from?
Guy's and St Thomas' NHS Foundation Trust, Heartlands Hospital, Southmead Hospital (UK)
(updated 10/05/2021, previously:
1. Guy's Hospital (UK)
2. St Thomas’ Hospital (UK)
3. King’s College Hospital (UK)
4. Musgrove Park Hospital (UK))

When is the study starting and how long is it expected to run for?
June 2015 to March 2021 (updated 10/05/2021, previously: June 2020)

Who is funding the study?
Novo Nordisk Limited (UK & Ireland)

Who is the main contact?
Ms Gemma Cutting
gemma.cutting@gstt.nhs.uk

# Contact information

### Type(s)
Public

### Contact name
Ms Gemma Cutting

### Contact details
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# Additional identifiers

### Clinical Trials Information System (CTIS)
2015-005402-11

### Protocol serial number
32498

# Study information

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

### Acronym
GLIDE

### Study objectives
The aim of this study is to evaluate the impact of liraglutide plus laparoscopic adjustable gastric band (LAGB) on diabetes control.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
London – Westminster Research Ethics Committee, 20/07/2016, ref: 16/LO/1144

### Primary study design
Interventional

### Study design
Randomised; Interventional; Design type: Treatment, Drug

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Specialty: Diabetes, Primary sub-specialty: Type 2; UKCRC code/ Disease: Metabolic and Endocrine/ Diabetes mellitus

### Interventions
Following laparoscopic adjustable gastric band (LAGB), patients will be randomised to receive liraglutide or placebo. Randomisation will be carried out by a computer generated

randomisation package. Patients will be stratified by duration of diabetes, BMI, centre and use of insulin through minimisation with a random component to ensure balance between treatment arms. Patients will be assigned to either injectable Liraglutide treatment or injectable placebo. Liraglutide (or placebo) will be titrated as recommended to the maximum tolerated dose or 1.8 mg. Dose escalation will be based on tolerability of previous dose. Participants will inject liraglutide/placebo daily for 6 months (including titration phase). Participants will then be followed up for a further 6 months after they have stopped taking the intervention.

### Intervention Type
Drug

### Drug/device/biological/vaccine name(s)
Liraglutide

### Primary outcome(s)
Difference in glycated haemoglobin (HbA1C) is measured using a glycated haemoglobin blood test at baseline and 6 months.

### Key secondary outcome(s)
1. Difference in glycated Haemoglobin (HbA1c) is measured using a glycated haemoglobin blood test at baseline and 12 months
2. Percentage of patients achieving diabetes remission comprising a HbA1c level of less than 6.5% and off all diabetes medications is measured by HbA1c blood test and clinical review /patient interview at months 3, 6, 9 and 12.
3. Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) is measured using fasting glucose, insulin and c-peptide blood tests at baseline, 6 and 12 months
4. Number of reported hypoglycaemic episodes are measured by clinical interview at months 3, 6, 9 and 12.
5. Anthropometric measures and body composition (height, weight, waist and neck circumference, BMI and Bioimpedance (Body Fat via Bioelectrical Impedance)) are measured at baseline, 3, 6 and 12 months
3. Physical activity levels are recorded using the General Physical Activity Questionnaire at baseline, 6 and 12 months
4. Cardiovascular disease risk factors (Systolic and Diastolic BP; total cholesterol, HDL-cholesterol, LDL-cholesterol and Triglyceride) are measured using a sphygmomanometer and blood testing at baseline, 3, 6 and 12 months
5. Quality of life is measured using the Impact of Weight on Quality of Life-Lite (IWQoL-Lite) Questionnaire, at baseline, 3, 6 and 12 months
6. Depression, anxiety and emotional distress is measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 6 and 12 months.
6. Adverse event rates recorded by clinical interview at baseline, 3, 6 and 12 months

### Completion date
31/03/2021

## Eligibility

### Key inclusion criteria
1. Adult patients with type 2 diabetes
2. HbA1c ≥6.5% and <11% at screening
3. Age 18-70 years

4. Patients with a BMI equal to or above 30kg/m2 (or 27kg/m2 and of Asian family origin) at screening
5. Patients undergoing LAGB based on NICE criteria and multidisciplinary assessment
6. Written informed consent to participate

## Participant type(s)
Patient

## Healthy volunteers allowed
No

## Age group
Adult

## Lower age limit
18 Years

## Upper age limit
70 Years

## Sex
All

## Key exclusion criteria
1. Patients with type 1 diabetes (based on clinical history)
2. Patients who refuse or are unable to have injectable treatment post operatively
3. Patients with any disability preventing use of treatment
4. Patients with known delayed gastric emptying (diagnosed by clinical history and judgment)
5. Any contraindication to liraglutide use (inflammatory bowel disease, ketosis, diabetic gastroparesis (based on clinical assessment), DPP-4 inhibitors, pregnancy and breast-feeding, renal impairment (eGFR < 30mL/min/1.73m2) and hepatic impairment; acute pancreatitis (persistent, severe abdominal pain))
6. Type 2 diabetes controlled purely through diet
7. Pregnancy or breastfeeding or planning to become pregnant during the study period and women of childbearing age who are not using adequate contraceptive methods (defined as: established use of oral, injected or implanted hormonal methods of contraception; placement of intrauterine device or intrauterine system; barrier methods of contraception (condom or occlusive cap with spermicidal foam/gel/film/cream/suppository); female sterilisation; male sterilisation (where partner is the sole partner of subject); true abstinence (when in line with preferred and usual lifestyle)
8. Personal or family history of thyroid cancer or multiple endocrine neoplasia
9. History of previous pancreatitis
10. Administration of a GLP-1 agonist or DPP-IV inhibitor after a time-point one week prior to surgery
11. Patients who display insufficient understanding of the trial procedures following reasonable attempts by the investigator to provide information, at the discretion of the investigator

## Date of first enrolment
30/11/2016

## Date of final enrolment

31/03/2020

# Locations

### Countries of recruitment
United Kingdom

England

### Study participating centre
### Guy's and St Thomas' NHS Foundation Trust
Great Maze Pond
London
United Kingdom
SE1 9RT

### Study participating centre
### Heartlands Hospital
Heart of England NHS Foundation Trust
Bordesley Green East
Birmingham
United Kingdom
B9 5SS

### Study participating centre
### Southmead Hospital
North Bristol NHS Trust
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB

# Sponsor information

### Organisation
NIHR Guy's & St Thomas' NHS Foundation Trust (GSTFT)/King’s College London (KCL) Biomedical Research Centre

### ROR
https://ror.org/00j161312

# Funder(s)

### Funder type
Research organisation

### Funder Name
Novo Nordisk Limited (UK & Ireland)

# Results and Publications

### Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

### IPD sharing plan summary
Data sharing statement to be made available at a later date

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| HRA research summary | | | 28/06/2023 | No | No |