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	2011-001538-41
Trial protocol	GB
Global end of trial date	04 June 2014

Results information

Result version number	v1 (current)
This version publication date	28 August 2020
First version publication date	28 August 2020
Summary attachment (see zip file)	Summary - 2011-001538-41 (Summary - 2011-001538-41.pdf)

Trial information

Trial identification

Sponsor protocol code	RG_11-056

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	University of Birmingham
Sponsor organisation address	Edgbaston, Birmingham, United Kingdom,
Public contact	Research Governance Team, University of Birmingham, researchgovernance@contacts.bham.ac.uk
Scientific contact	Research Governance Team, University of Birmingham, researchgovernance@contacts.bham.ac.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	04 June 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	04 June 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The study will seek to address the following major questions regarding liraglutide combined with the gastric band:

When compared with band alone, will the combination treatment result in greater -

1. diabetes resolution
2. weight loss and reduction in body fat
3. change in quality of life
4. reduction in cardiovascular risk

Planned Interventions

Laparoscopic gastric band plus subcutaneous daily:

1. Placebo: Solution for injection in 3 mL pre-filled pen
2. Liraglutide 6.0 mg/mL solution for injection in 3 mL pre-filled pen

Primary Outcome

The primary outcome will be the percentage of patients with diabetes resolution defined as fasting plasma glucose of <7.0 mmol/L (WHO) and off all diabetes medications.

Protection of trial subjects:

Inclusion criteria - All adult diabetes patients (type 2 diabetes, 18-70 y, male and female, HbA1c ≥ 6.5% and < 11%) with BMI equal or above 35 Kg/m2 who are undergoing LAGB based on NICE criteria and multidisciplinary assessment and clinically suitable for liraglutide therapy will be included. A full medical history (including medications) and a medical examination will be carried out at enrolment.
Exclusion criteria - 1. Patients who refuse or unable to have injectable treatment post operatively
2. Patients with disability preventing use of treatment
3. Patients who cannot give consent
4. Patients with known delayed gastric emptying (diagnosed by clinical history and judgment)
5. Patients taking any medications that may interact with the trial medication (DPP4- inhibitors and exenetide)
6. Any contraindication stated in the BNF to liraglutide use (inflammatory bowel disease, ketosis, diabetic gastroparesis (based on clinical assessment), pregnancy and breast-feeding, renal impairment (eGFR < 60mL/min/1.73m2) and hepatic impairment; discontinue treatment if symptoms of acute pancreatitis (persistent, severe abdominal pain))
7. Previous treatment with GLP-1
8. Purely diet controlled or insulin treatment ≥ 5 years
9. Patients with HbA1C ≥ 11%
10. Pregnancy or breastfeeding or planning to become pregnant during the study period
11. Personal or family history of thyroid cancer or multiple endocrine neoplasia
12. History of previous pancreatitis

Withdrawal criteria - 1. Participants can withdraw from the study at any time
2. Inability to tolerate trial treatment
3. Pregnancy
4. Severe episodes of hypoglycaemia despite stoppage of hypoglycaemic medication
5. Acute pancreatitis
6. Deterioration in renal function (eGFR<60mL/min)

Background therapy: -	
Evidence for comparator: -	
Actual start date of recruitment	04 June 2014
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: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This trial was terminated early. No patients were approached, screened, recruited or randomised to the trial.
Regarding recruitment data, for the purposes of data entry 99999 is referring to not applicable or 0 participants as no participants were enrolled/recruited to this trial.

Pre-assignment

Screening details:

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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

Blinding implementation details:

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Arms

Arm title	Overall trial

Arm description:

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Arm type	Overall
Investigational medicinal product name	Liraglutide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

This trial was terminated early. No patients were approached, screened, recruited or randomised to the trial.
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Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled pen
Routes of administration	Subcutaneous use

Dosage and administration details:

This trial was terminated early. No patients were approached, screened, recruited or randomised to the trial.
Regarding recruitment data, for the purposes of data entry 99999 is referring to not applicable or 0 participants as no participants were enrolled/recruited to this trial.

Number of subjects in period 1	Overall trial
Started	99999
Completed	99999

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description:

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Regarding recruitment data, for the purposes of data entry 99999 is referring to not applicable or 0 participants as no participants were enrolled/recruited to this trial.

Reporting group values	Overall trial	Total	
Number of subjects	99999	99999	
Age categorical			
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Units: Subjects			
Not applicable	99999	99999	
Gender categorical			
This trial was terminated early. No patients were approached, screened, recruited or randomised to the trial. Regarding recruitment data, for the purposes of data entry 99999 is referring to not applicable or 0 participants.			
Units: Subjects			
Not applicable	99999	99999	

End points

End points reporting groups

Reporting group title	Overall trial

Reporting group description:

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Primary: Not applicable

End point title	Not applicable[1]

End point description:

This trial was terminated early. No patients were approached, screened, recruited or randomised to the trial. Regarding recruitment data, for the purposes of data entry 99999 is referring to not applicable or 0 participants.

End point type	Primary

End point timeframe:

This trial was terminated early. No patients were approached, screened, recruited or randomised to the trial. Regarding recruitment data, for the purposes of data entry 99999 is referring to not applicable or 0 participants.

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: No statistical analyses have been specified as the trial was terminated early. No patients were approached, screened, recruited or randomised to the trial.
Regarding recruitment data, for the purposes of data entry 99999 is referring to not applicable or 0 participants.

End point values	Overall trial			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: Not applicable	99999			

Notes:

[2] - Regarding recruitment data for the purposes of data entry 99999 is referring to not applicable or 0

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

This section is not applicable. The trial was terminated early and did not recruit or enrol any participants.

Adverse event reporting additional description:

This trial was terminated early. No patients were approached, screened, recruited or randomised to the trial. Regarding recruitment data, for the purposes of data entry 99999 is referring to not applicable or 0 participants.

Assessment type	Systematic

Dictionary used

Dictionary name	N/A.
Dictionary version	0

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: No adverse events have been specified as the trial was terminated early. No patients were approached, screened, recruited or randomised to the trial.
Regarding recruitment data, for the purposes of data entry 99999 is referring to not applicable or 0 participants.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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.

This trial was terminated early. No patients were approached, screened, recruited or randomised to the trial.
Regarding recruitment data, for the purposes of data entry 99999 is referring to not applicable or 0 participants.

Notes: