

A comparative study of the effects of Liraglutide and Acarbose on glycaemic control, weight and Health Related Quality Of Life (HRQOL) in Overweight type 2 Diabetic patients on Oral Hypoglycaemic Agents (OHAs) and high doses of insulin.

Submission date 17/08/2010	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 31/08/2010	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 23/06/2015	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2010-020193-42

Protocol serial number

2010-020193-42

Study information

Scientific Title

An open label, randomised controlled trial of the effects of Liraglutide and Acarbose on glycaemic control, weight and Health Related Quality Of Life (HRQOL) in Overweight type 2 Diabetic patients on Oral Hypoglycaemic Agents (OHAs) and high doses of insulin

Acronym

Lirabose1

Study objectives

To evaluate the effectiveness of Liraglutide Versus Acarbose and standard treatment in type-2 Diabetic patients failing to achieve glycemic control on high dose insulin and oral hypoglycemic agents

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Research Ethics Committee for Wales, 06/09/2010, ref: 10/MREC09/20

Study design

Single-centre open-label three-arm randomised active-controlled parallel-group comparative trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 2 diabetes

Interventions

1. Group 1 Liraglutide
2. Group 2 Acarbose
3. Group 3 no intervention (standard treatment group for control)

Updated 23/06/2015: This trial has been discontinued due to poor recruitment.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Liraglutide, acarbose

Primary outcome(s)

1. Improvement in glycaemic control (assessed by measurement of HbA1c) as a result of addition of Liraglutide (a GLP analogue) or Acarbose (an oral anti-Diabetic drug), when compared with standard treatment.

Key secondary outcome(s)

Improvement in:

1. Weight
2. Health related quality of life, assessed by RAND-36 questionnaire at baseline and 52 weeks
3. Blood pressure
4. Total daily insulin dose
5. Hypoglycaemic episodes

Completion date

01/12/2012

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility**Key inclusion criteria**

1. Age > 18 years
2. Male or female

In addition, patients should fulfil all the following criteria at the randomization visit (visit 0):

3. Type II Diabetic patients with suboptimal glycaemic control despite on high doses (1 unit/kg /day OR 100units/day) of insulin
4. Glycated Haemoglobin (HbA1c) $\geq 7.5\%$
5. Body Mass Index (BMI) ≥ 29
6. On, at least: Metformin ($\geq 1.5\text{G/day}$) and Sulfonylureas (SU) (Gliclazide $\geq 240\text{mg/day}$ or Glimepride $\geq 4\text{mg/day}$)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Previous history of: Myocardial infarction (MI) (in last 12 months)
2. Congestive Cardiac Failure (New York Heart Association [NYHA] class III or IV)
3. Stage II, III & IV Chronic kidney disease
4. Abnormal Alanine Aminotransferase (ALT) (> 3fold Upper Limit of Normal [ULN] at baseline)
5. Hypoglycaemia unawareness OR recurrent hypos requiring 3rd party assistance
6. Uncontrolled Hypertension (Blood Pressure [BP] > 180/100mmHg)
7. Pregnant OR likelihood of pregnancy during the study
8. Patients currently on OR treated in the last 12-months with a glitazone, Dipeptidyl Peptidase IV (DPP-IV), Glucagon-Like Peptide (GLP) analogue, acarbose or steroids
9. History of inflammatory bowel disease, colonic ulceration, previous abdominal surgery, history or presence of intestinal obstruction / hernia
10. Predisposition to intestinal obstruction
11. History of Diabetic ketoacidosis, gastroparesis and pancreatitis
12. Females lactating or breastfeeding
13. History of allergic reaction or hypersensitivity to Liraglutide, Acarbose or insulin
14. Age more than 75 years
15. Type-1 Diabetes mellitus
16. History of thyroid cancer
17. Patients currently on Warfarin
18. Patients on sulphonylureas other than Gliclazide or Glimepride

Date of first enrolment

01/08/2010

Date of final enrolment

01/12/2012

Locations

Countries of recruitment

United Kingdom

Wales

Study participating centre

West Wales Hospital

Carmarthen

United Kingdom

SA31 2AF

Sponsor information

Organisation

West Wales Hospital (UK)

ROR

<https://ror.org/01cs14q41>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

West Wales Hospital Diabetes Centre (UK) - research fund

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration