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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

Registration date
31/08/2010

Overall study status
Stopped

Last Edited
23/06/2015

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

EudraCT/CTIS number
2010-020193-42

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 hypoglcemic 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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Type 2 diabetes

Interventions
1. Group 1 Lirglutide
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 measure
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.

Secondary outcome measures
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

Overall study start date
01/08/2010

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) ≥ 7.5%
5. Body Mass Index (BMI) ≥ 29
6. On, at least: Metformin (≥ 1.5G/day) and Sulfonylureas (SU) (Gliclazide ≥ 240mg/day or Glimepride ≥ 4mg/day)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Total 66 (22 x 3 groups)

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, gasteroparesis 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)

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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration