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Low-carbohydrate high-protein diet in obese diabetic subjects

Submission date	Recruitment status	[ ] Prospectively registered
05/09/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/09/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
29/06/2016	Nutritional, Metabolic, Endocrine	[ ] 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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Alterations in the macronutrient content of the diet and effects on body composition, cardiovascular disease risk and the control of energy metabolism in obese patients with type II diabetes mellitus

Study objectives
To assess the weight loss achieved after 12 months on one of two hypoenergetic low-carbohydrate, high-protein diets (the protein sparing modified fast compared to commercial diet provided by the Go Lower company).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the North of Scotland Research Ethics Committees on the 15th April 2008 (ref: 08/S0801/54).

Study design
Single centred randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Obese, type 2 diabetics

Interventions
Patients will be assigned to either the protein sparing modified fast (PSMF) or the Go Lower diet. In both instances, patients will be given oral and written information about the diet. Patients on Go Lower will be given weekly food packs while the patients on PSMF will prepare their own food. Patients will be seen at 2 and 4 weeks post-randomisation and then monthly for a total of 1 year.

Intervention Type
Other

Phase

Not Specified

Primary outcome measure
Weight change, measured in kilograms at baseline, 3, 6, 9 and 23 months.

Secondary outcome measures
1. Changes in cardiovascular risk, measured by looking at total cholesterol, triacylglycerols, high density lipoprotein (HDL), low-density lipoprotein (LDL), C-reactive protein (mg/L), fasting glucose (all in mmol/L), fasting insulin (uU/ml), HbA1c (%), waist circumference (cm), blood pressure (mmHg)
2. Glycaemic control will be measured using fasting glucose, fasting insulin and HbA1c
3. Metabolic rate is being measured using the ventilated hood (Quark RMR machine) from COSMED
4. Liver function will be assessed by measuring albumin (g/L), total bilirubin (umol/L), alkaline phosphatase, alanine aminotransferase and gamma-glutamyl transferase (U/L). For kidney function we will measure urea (mmol/L) and creatinine (umol/L) and calculate the estimated glomerular filtration.
5. Quality of life, measured using the following questionnaires: Weight: Decisional Balance, Orwell 97, Diabetes treatment satisfaction questionnaire, Audit of Diabetes-Dependent quality of life, Lee fatigue scale, General Practice Physical activity questionnaire, Major (ICD-10) depression inventory and the Epworth Sleepiness Scale
6. Changes in adipokines

These will all be measured at baseline, 3, 6, 9 and 23 months.

Overall study start date
15/04/2008

Completion date
15/04/2010

Eligibility

Key inclusion criteria
1. Men and women between 18 and 75 years of age
2. Body Mass Index (BMI) greater than or equal to 30 kg/m^2
3. Poorly controlled type II diabetes mellitus (HbA1c greater than or equal to 7.5%)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. A history or current renal, hepatic disease or cancer
2. Have had a major coronary event in the last 6 months
3. Diet related diseases
4. On antidepressant or obesity-related pharmacotherapy
5. Current pregnancy or lactating

Date of first enrolment
15/04/2008

Date of final enrolment
15/04/2010

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
The Robert Gordon University
Aberdeen
United Kingdom
AB25 1HG

Sponsor information

Organisation
The Robert Gordon University (UK)

Sponsor details
Centre for Obesity Research and Epidemiology
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Sponsor type

University/education

Website
http://www.rgu.ac.uk/

ROR
https://ror.org/04f0qj703

Funder(s)

Funder type
Industry

Funder Name
Go Lower Limited (UK)

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