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Comparison of intermittent use of a very low calorie diet (VLC) versus Orlistat for weight maintenance in the management of obese patients with type 2 diabetes

Submission date
12/09/2003

Recruitment status
No longer recruiting

Registration date
12/09/2003

Overall study status
Completed

Last Edited
05/12/2014

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0077107001

Study information

Scientific Title
Comparison of intermittent use of a very low calorie diet (VLC) versus Orlistat for weight maintenance in the management of obese patients with type 2 diabetes

Study objectives
We postulate that recurrent periods of VLCD (Pulsed VLCD) may be as effective for weight maintenance as Orlistat in managing obesity in Type 2 Diabetes Mellitus.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
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
Nutritional, Metabolic, Endocrine: Obesity

Interventions
After medical and dietetic assessment, patients will receive a VLC diet (approx 700 cal) for no more than 3 months until 10 kg or 12% weight loss is achieved. Patients will be randomised to either 'Pulsed VLCD' or Orlistat 120 mg. tds and followed up over 12 months. The schedule of visits will be Week 0, 2, 4, 8, 12, 16, 20, 36, 52, with telephone visits at weeks 24, 28,and 32. At each visit patients will have a dietary review, weight and blood pressure check. The ADDPoL, WBQ22 and DSTQs and DTSQC questionnaire will be used to assess quality of life, well-being and diabetic treatment satisfaction.

Intervention Type
Mixed

Primary outcome measure
1. Weight loss, improvement of cardiovascular risk
2. Improvement of blood pressure (BP)
3. Improvement of psychological outcome

Secondary outcome measures
Not provided at time of registration

Overall study start date
20/02/2002

Completion date
01/09/2004

Eligibility

Key inclusion criteria
1. Patients with type 2 diabetes attending the Jenny O'Neill Diabetes Centre and patients attending Primary Care diabetes clinics
2. Who are overweight (Body Mass Index [BMI] >28)
3. Who are either on maximal or near maximal doses of oral hypoglycaemics or are insulin treated but have poor control (HbA1c >7.59) and are motivated to lose weight

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
20/02/2002

Date of final enrolment
01/09/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Southern Derbyshire Acute Hospitals NHS Trust
Derby
United Kingdom
DE1 2QY

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Southern Derbyshire Acute Hospitals NHS Trust (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