

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	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 05/12/2014	Condition category Nutritional, Metabolic, Endocrine	☐ 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

Contact name

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Southern Derbyshire Acute Hospitals NHS Trust

Derby

United Kingdom

DE1 2QY

Sponsor information

Organisation

Department of Health (UK)

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Southern Derbyshire Acute Hospitals NHS Trust (UK)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration