# 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	Recruitment status	<ul><li>Prospectively registered</li></ul>
12/09/2003	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
12/09/2003	Completed	Results
Last Edited	Condition category	Individual participant data
05/12/2014	Nutritional, Metabolic, Endocrine	<ul><li>Record updated in last year</li></ul>

## Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr A Scott

#### Contact details

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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