Subcutaneous oxyntomodulin reduces bodyweight in overweight subjects

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/07/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/07/2005	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
06/02/2015	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 071446

Study information

Scientific Title

Subcutaneous oxyntomodulin reduces body-weight in overweight subjects

Study objectives

The effect of self-administered subcutaneous oxyntomodulin on overweight volunteers was investigated in a four-week community-based study. We hypothesised oxyntomodulin would reduce body weight and appetite.

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

Obesity

Interventions

Healthy overweight volunteers self-administered either saline or oxyntomodulin subcutaneously for four weeks, three times daily, 30 minutes before each meal, in a randomised double-blind parallel-group protocol. The volunteers were asked to maintain their regular diet and level of physical exercise. Subjects' body weight, energy intake and levels of adipose hormones were assessed at the start and end of the study.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Oxyntomodulin

Primary outcome measure

Body weight, energy intake and adipose hormones.

Secondary outcome measures

No secondary outcome measures

Overall study start date

02/01/2004

Completion date

31/08/2004

Eligibility

Key inclusion criteria

- 1. Healthy male and female volunteers, aged 18 to 55 years
- 2. A stable Body Mass Index (BMI) between 25 and 40 kg/m^2

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

26

Key exclusion criteria

- 1. Abnormal eating behaviour
- 2. A current medical condition
- 3. Abnormal ElectroCardioGram (ECG)
- 4. Abnormal blood tests
- 5. Pregnancy or breastfeeding
- 6. Blood donation or participation in another research study within the last three months

Date of first enrolment

02/01/2004

Date of final enrolment

01/07/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre Hammersmith Hospital London United Kingdom W12 0NN

Sponsor information

Organisation

Imperial College London (UK)

Sponsor details

Level 2, Faculty Building Clinical Research Office South Kensington campus London England United Kingdom SW7 2AZ

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clinical.researchoffice@imperial.ac.uk

Sponsor type

University/education

ROR

https://ror.org/041kmwe10

Funder(s)

Funder type

Charity

Funder Name

Wellcome Trust

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

United Kingdom

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2005		Yes	No