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Subcutaneous oxyntomodulin reduces body-weight in overweight subjects

Submission date	Recruitment status	[_] Prospectively registered
22/07/2005	No longer recruiting	[_] 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

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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
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England
United Kingdom
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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