

A study investigating rimonabant and diet in overweight subjects

Submission date 05/06/2008	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2008	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 09/01/2018	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
RGHT000540

Study information

Scientific Title

A study investigating rimonabant versus placebo in conjunction with a strict low-fat weight reduction diet in overweight and obese subjects: effects on glucose and lipid metabolism and cardiovascular risk

Study objectives

Rimonabant has beneficial effects on metabolic parameters over and above that explained by weight loss alone.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Office for Research Ethics Committee Northern Ireland (ORECNI). Date of approval: 04/06/2008 (ref: 08/NIR02/31)

Study design

Double-blind, randomised, placebo-controlled, single-centre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Overweight and obese subjects at risk of type 2 diabetes

Interventions

Subjects will be randomised to one of two arms. Study arms are identical in their strict low fat weight reduction diet but will differ in medication. Subjects on one arm will take 20 mg rimonabant (oral) daily and those on the other arm will take placebo.

Duration of interventions: 8 weeks

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Rimonabant

Primary outcome measure

The following will be assessed at baseline and 8 weeks (end of interventions):

1. Insulin resistance, assessed using the euglycaemic hyperinsulinaemic glucose clamp technique
2. Weight

Secondary outcome measures

The following will be assessed at baseline and 8 weeks (end of interventions):

1. Meal tolerance tests
2. Glycaemic control
3. Vascular compliance
4. Body composition
5. Plasma lipids
6. Adipokines
7. Fat biopsies

Overall study start date

01/08/2008

Completion date

01/08/2010

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility**Key inclusion criteria**

1. Both males and females, age >18 years
2. Body mass index (BMI) >27 kg/m²

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

24

Key exclusion criteria

1. Pregnant women/ breastfeeding mothers
2. Women of childbearing age unwilling to use appropriate contraception
3. Subjects with history of depression or anxiety
4. Subjects with history of significant cardiac, renal or hepatic dysfunction
5. Subjects concurrently on weight loss medication

Date of first enrolment

01/08/2008

Date of final enrolment

01/08/2010

Locations

Countries of recruitment

Northern Ireland

United Kingdom

Study participating centre

The Regional Centre for Endocrinology and Diabetes

Belfast

United Kingdom

BT12 6BA

Sponsor information

Organisation

Belfast Health and Social Care Trust (UK)

Sponsor details

The Royal Hospitals

Royal Victoria Hospital

Grosvenor Road

Belfast

Northern Ireland

United Kingdom

BT12 6BA

Sponsor type

Hospital/treatment centre

Website

<http://www.belfasttrust.hscni.net/index.html>

ROR

<https://ror.org/02tdmfk69>

Funder(s)

Funder type

Government

Funder Name

Northern Ireland Research and Development Office (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