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A study investigating rimonabant and diet in overweight subjects

Submission date	Recruitment status	[ ] Prospectively registered
05/06/2008	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2008	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/01/2018	Nutritional, Metabolic, Endocrine	[ ] 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

Protocol serial number
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)

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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/m^2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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
United Kingdom

Northern Ireland

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)

ROR
https://ror.org/02tdmfk69

Funder(s)

Funder type
Government

Funder Name
Northern Ireland Research and Development Office (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration