ISRCTN75758249 https://doi.org/10.1186/ISRCTN75758249

Biological variation of insulin resistance, testosterone and cardiovascular risk factors in women with polycystic ovary syndrome: modification with rimonabant compared to metformin

Submission date	Recruitment status
23/10/2007	No longer recruiting
Registration date	**Overall study status**
31/10/2007	Completed
Last Edited	**Condition category**
18/01/2012	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R0391

Study information

Scientific Title

Study objectives
1. To show that rimonabant treatment is superior to metformin in reducing mean insulin resistance, high androgen levels and cardiovascular risk indices in women with PolyCystic Ovarian Syndrome (PCOS)
2. To show that rimonabant treatment is superior to metformin in reducing the fluctuations in biological variation of insulin resistance in PCOS

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from Hull and East Riding Local Research Ethics Committee on the 19th December 2006 (ref: 06/Q1104/115).

Study design
Randomised, open-label, parallel study.

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
PolyCystic Ovary Syndrome (PCOS)

Interventions
Rimonabant 20 mg (oral) daily or metformin 500 mg (oral) three times a day (tds) for 3 months.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The following will be assessed at 3 months:
1. The HOMeostasis model Assessment of Insulin Resistance (HOMA-IR)
2. Testosterone

Secondary outcome measures
The following will be assessed at 3 months:
1. Waist cirumference
2. Free androgen index

Overall study start date
01/09/2006

Completion date
01/01/2008

Eligibility

Key inclusion criteria
1. Polycystic ovarian syndrome
2. Body Mass Index (BMI) greater than 30 kg/m^2

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
20

Key exclusion criteria
1. Patient should not be on any drugs
2. Unwilling for General Practitioner (GP) to be informed
3. Diabetic patients
4. Uncompensated hypothyroidism
5. Patients not on barrier contraception
6. History of psychiatric disorder or severe depression
7. Chronic renal failure

Date of first enrolment
01/09/2006

Date of final enrolment

01/01/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Michael White Diabetes Centre
Hull
United Kingdom
HU3 2JZ

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
c/o Mrs Nina Dunham
R&D admin portacabin
Castle Hill Hospital
Castle Road
Cottingham, East Yorkshire
Hull
England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

Website
http://www.hey.nhs.uk/

ROR
https://ror.org/01b11x021

Funder(s)

Funder type

University/education

Funder Name
University of Hull (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2009		Yes	No