# 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	<ul><li>Prospectively registered</li></ul>
23/10/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
31/10/2007	Completed	[X] Results
Last Edited	Condition category	[] Individual participant data
18/01/2012	Nutritional, Metabolic, Endocrine	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Prof Stephen Atkin

#### Contact details

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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

## 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

### 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