

# Biological variation of insulin resistance on polycystic ovarian syndrome and effect of treatment

**Submission date**

25/01/2007

**Recruitment status**

No longer recruiting

Prospectively registered

Protocol

**Registration date**

28/02/2007

**Overall study status**

Completed

Statistical analysis plan

Results

**Last Edited**

29/03/2012

**Condition category**

Nutritional, Metabolic, Endocrine

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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**Contact details**

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## Additional identifiers

**Protocol serial number**

07/03/117

## Study information

**Scientific Title**

Biological factors of insulin resistance and cardiovascular risk factors in women with polycystic ovarian syndrome: modification with diet, metformin, pioglitazone and orlistat

## **Study objectives**

To determine if insulin resistance variability and the associated cardiovascular risk factor variability is affected by weight loss aided by the use of diet, orlistat, or by the insulin sensitising agents metformin, pioglitazone or soy in patients with polycystic ovarian syndrome (PCOS).

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Ethics approval received from Hull and East Riding Local Research Ethics Committee (ref: 07/03 /117).

## **Study design**

Prospective study

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Polycystic ovarian syndrome

## **Interventions**

Treatment with either metformin, orlistat or pioglitazone. Dietary advice was based on the recommendation by the "British Heart Foundation's Guide for Healthy Eating" and for the soy treatment arm, a sachet containing 132 mg of phytoestrogen consisting mainly of genistein and daidzein in 30 g of soy protein was given.

After baseline blood assessments, patients were randomised to either:

1. Dietary advice only
2. Metformin (500mg three times daily)
3. Orlistat (120mg three times daily)
4. Pioglitazone (45mg once daily)
5. Soy phytoestrogen

Duration of treatment was for 3 months after which they came back for phase two of the study where further blood sampling was carried out.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome(s)**

Reduction in insulin resistance

## **Key secondary outcome(s)**

Reduction in hyperandrogenaemia

**Completion date**

30/09/2006

## Eligibility

**Key inclusion criteria**

The diagnosis of PCOS will be based on evidence of hyperandrogenemia (Free androgen index > 8, with a history of oligomenorrhea and hirsutism or acne. Non classical 21-hydroxylase deficiency, hyperprolactinemia, and androgen secreting tumors will be excluded by appropriate tests before the diagnosis of PCOS will be made. Transvaginal ultrasound will also be performed to confirm the diagnosis of PCOS

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

Female

**Key exclusion criteria**

1. No subjects will be taking any medication currently or for the preceding six months
2. No concurrent illness
3. Patients not wishing to allow disclosure to their GPs

**Date of first enrolment**

06/08/2004

**Date of final enrolment**

30/09/2006

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Centre for Diabetes and Endocrinology**

Hull

United Kingdom

HU3 2RW

# Sponsor information

## Organisation

Hull and East Yorkshire Hospitals NHS Trust (UK)

## ROR

<https://ror.org/01b11x021>

# Funder(s)

## Funder type

University/education

## Funder Name

University of Hull (UK) - Diabetes endowment fund

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/02/2009		Yes	No