

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

Submission date

25/01/2007

Recruitment status

No longer recruiting

Registration date

28/02/2007

Overall study status

Completed

Last Edited

29/03/2012

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ Results

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

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 measure

Reduction in insulin resistance

Secondary outcome measures

Reduction in hyperandrogenaemia

Overall study start date

06/08/2004

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

Age group

Not Specified

Sex

Female

Target number of participants

40

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

England

United Kingdom

Study participating centre

Centre for Diabetes and Endocrinology

Hull

United Kingdom

HU3 2RW

Sponsor information

Organisation

Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details

Hull Royal Infirmary

Anlaby Road

Hull

England

United Kingdom

HU3 2JZ

Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)

Funder type

University/education

Funder Name

University of Hull (UK) - Diabetes endowment fund

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	01/02/2009		Yes	No