ISRCTN58369615 https://doi.org/10.1186/ISRCTN58369615

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

Submission date	Recruitment status
25/01/2007	No longer recruiting
Registration date	**Overall study status**
28/02/2007	Completed
Last Edited	**Condition category**
29/03/2012	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

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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 advise 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