

Biological Variation of insulin resistance in normal ovulating women and PolyCystic Ovarian Syndrome

Submission date

25/01/2007

Recruitment status

No longer recruiting

Registration date

28/02/2007

Overall study status

Completed

Last Edited

03/05/2011

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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Additional identifiers

Protocol serial number

02/98/249

Study information

Scientific Title**Acronym**

Biological variation in PCOS

Study objectives

Women with polycystic ovarian syndrome has a higher and more variable insulin resistance than controls

Ethics approval required

Old ethics approval format

Ethics approval(s)

Hull and East Riding Local Research Ethics Committee. LREC number : 02/98/249

Primary study design

Observational

Study design

Comparison study

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Polycystic ovarian syndrome

Interventions

Primary outcome was the comparison of insulin resistance in polycystic ovarian syndrome and controls. Venous blood was taken for measurement of insulin and glucose levels, and insulin resistance was calculated by HOMA-IR (insulin x glucose /22.5).

Secondary outcome was the biological variation of insulin resistance in polycystic ovarian syndrome and controls. Insulin resistance was calculated by HOMA-IR as above, and calculation of biological variation was done on 10 consecutive HOMA-IR taken at 4-day intervals.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Comparison of Insulin resistance in polycystic ovarian syndrome and controls

Key secondary outcome(s)

Comparison of biological variation of polycystic ovarian syndrome with controls

Completion date

31/12/2004

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

28/02/2002

Date of final enrolment

31/12/2004

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

Diabetes endowment Fund, University of Hull (UK)

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?
Results article	results	01/04/2002		Yes	No