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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
[X] Results
[_] 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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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Comparison study

Primary study design
Observational

Secondary study design
Cross-section survey

Study setting(s)
Hospital

Study type(s)
Not Specified

Participant information sheet

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 measure
Comparison of Insulin resistance in polycystic ovarian syndrome and controls

Secondary outcome measures
Comparison of biological variation of polycystic ovarian syndrome with controls

Overall study start date
28/02/2002

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

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
28/02/2002

Date of final enrolment
31/12/2004

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
Diabetes endowment Fund, 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	01/04/2002		Yes	No