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Database of patients with polycystic ovary syndrome and healthy women

Submission date	Recruitment status	[_] Prospectively registered
09/05/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/05/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/02/2018	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Polycystic ovary syndrome (PCOS) is a common hormone problem in young women and, as a result of it, they can experience irregular periods, reduced fertility, acne and increased body hair. Research suggests that they could have a higher risk of diabetes, because of their increased weight and also because they seem to have higher insulin levels. There is also the concern that there is an increased risk of cardiovascular disease (hypertension, heart attack, and stroke). Research shows that an increasing number of illnesses have a genetic element. Diabetes, asthma, certain heart conditions are now thought to have a genetic component. Early research suggests that PCOS might have a genetic component as well. We are comparing patients with polycystic ovary syndrome to women without polycystic ovary syndrome who are premenopausal.

Who can participate?
Women with polycystic ovary syndrome as well as healthy women are invited to participate.

What does the study involve?
The study includes two visits to Diabetes research centre, Hull Royal Infirmary. You will be requested to fill questionnaires as well as blood (approx 7 tablespoons of blood sample will be taken), urine, saliva and sebum will be collected. We will also arrange for ultrasound examination as well as tests to check the function of blood vessels.

What are the possible benefits and risks of participating?
For most people needle punctures for blood draws do not cause any serious problems. Some people feel faint, and there may be some pain and bruising (or, very rarely, infection) where the needle goes in. Please, let us know if you have had a problem in the past. The study will not bring direct benefits to you, but the information we get from this study may help to reduce the risks of heart attacks and stroke in patients with polycystic ovary syndrome. Your contribution and participation in this study will advance the knowledge on the causes of PCOS and related conditions including obesity and type 2 diabetes which could be helpful for the development of treatments or preventive measures.

Where is the study run from?
The study is conducted in Clinical Research Unit, Michael White Diabetes Centre, Hull Royal Infirmary, Hull, UK

When is study starting and how long is it expected to run for?
The study started in 2011 and we plan to recruit by 2013.

Who is funding the study?
This study is supported by a grant from Hull York Medical School

Who is the main contact?
Dr Thozhukat Sathyapalan
thozhukat.sathyapalan@hyms.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Thozhukat Sathyapalan

Contact details
Michael White Diabetes Centre
Hull Royal Infirmary
220-236 Anlaby Road
Hull
United Kingdom
HU3 2RW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R1042 10/H0906/17

Study information

Scientific Title
Genetic database of patients with polycystic ovary syndrome and healthy women: a cohort study

Study objectives

This is a database for polycystic ovary syndrome (PCOS) and control women for genomic studies and elucidating biological pathways underlying the development of the PCOS phenotype and to identify the genetic factors associated with the increased cardiovascular risk that these patients have.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval granted by Newcastle 1 REC, UK, 10/01/2012, ref: 10/H0906/17

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Screening

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 ovay syndrome

Interventions
All subjects will be asked to arrive fasting in the morning. Informed consent will be taken. Blood, saliva, sebum and urine samples will be collected during the follicular phase of menstrual cycle if the cycles are regular. All subjects will be asked to fill out a questionnaire. Subjects will then undergo further history, physical exam and laboratory exams. All the samples and data including history as well as questionnaires will be stored securely linked anonymised. Transvaginal / transabdominal ultrasound and endo PAT as well as blood samples will be done in a seperate visit. Consent will be taken to contact back the patient if needed in the future for follow up.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Cardiovascular risk will be assessed by lipid profile, high-sensitivity C-reactive protein (hsCRP), 75g oral glucose tolerance test, HOMA and endo PAT

Secondary outcome measures
1. Genetic polymorphism: DNA samples will be extracted and studied for genetic polymorphisms
2. Hormonal parameters including free androgen index, Dehydroepiandrosterone sulfate (DHEAS), androstenedione and 17OH progesterone will be measured
3. Quality of life will be assessed using questionnaires including PCOS QoL questionnaire

Overall study start date
01/10/2011

Completion date
01/01/2013

Eligibility

Key inclusion criteria
1. PCOS subjects as per Rotterdam criteria
2. Age 18 to 40 years

Inclusion criteria - controls
1. Aged 18 to 40 years
2. Regular menstrual cycles 21 to 35 days
3. No clinical or biochemical evidence of hyperandrogenemia
4. Normal thyroid-stimulating hormone (TSH) and prolactin
5. No first degree relatives having polycystic ovary syndrome

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
500

Key exclusion criteria
1. Non-classical 21-hydroxylase deficiency
2. Hyperprolactinaemia
3. Cushing's disease
4. Androgen-secreting tumours

Date of first enrolment
01/10/2011

Date of final enrolment
01/01/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Michael White Diabetes Centre
Hull
United Kingdom
HU3 2RW

Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

Sponsor details
Mr James Illingworth
R&D Manager
Research & Development Department
Hull & East Yorkshire Hospitals NHS Trust
2nd Floor Daisy Building
Castle Hill Hospital
Cottingham
East Yorkshire
Hull
England
United Kingdom
HU16 5JQ

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01b11x021

Funder(s)

Funder type
University/education

Funder Name
Hull York Medical School (HYMS) (UK) - Pump Priming Grant

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	19/11/2015		Yes	No
Results article	results	01/12/2017		Yes	No
HRA research summary			28/06/2023	No	No