# Database of patients with polycystic ovary syndrome and healthy women

Submission date	Recruitment status	Prospectively registered	
Registration date	Overall study status	<ul> <li>Statistical analysis plan</li> </ul>	
22/05/2012	Completed	[X] Results	
Last Edited 13/02/2018	<b>Condition category</b> Nutritional, Metabolic, Endocrine	Individual participant data	

### 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

 Genetic polymorphism: DNA samples will be extracted and studied for genetic polymorphisms
 Hormonal parameters including free androgen index, Dehydroepiandrosterone sulfate (DHEAS), androstenedione and 170H progesterone will be measured
 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?
<u>Results article</u>	results	19/11/2015		Yes	No
<u>Results article</u>	results	01/12/2017		Yes	No
HRA research summary			28/06/2023	No	No