

# Database of patients with polycystic ovary syndrome and healthy women

|                                        |                                                                |                                                      |
|----------------------------------------|----------------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>09/05/2012   | <b>Recruitment status</b><br>No longer recruiting              | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                                | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>22/05/2012 | <b>Overall study status</b><br>Completed                       | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                                | <input checked="" type="checkbox"/> Results          |
| <b>Last Edited</b><br>13/02/2018       | <b>Condition category</b><br>Nutritional, Metabolic, Endocrine | <input type="checkbox"/> 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

### Protocol serial number

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

## **Primary study design**

Observational

## **Study design**

Observational cohort study

## **Study type(s)**

Screening

## **Health condition(s) or problem(s) studied**

Polycystic ovary 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 separate 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(s)**

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

## **Key secondary outcome(s)**

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

## **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**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**

United Kingdom

England

**Study participating centre**

Michael White Diabetes Centre

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**

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

**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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>      | results | 19/11/2015   |            | Yes            | No              |
| <a href="#">Results article</a>      | results | 01/12/2017   |            | Yes            | No              |
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |