# Atorvastatin in polycystic ovary syndrome (PCOS)

Submission date	Recruitment status  No longer recruiting	Prospectively registered	
03/04/2008		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
09/05/2008	Completed	[X] Results	
Last Edited	Condition category	[] Individual participant data	
15/07/2019	Nutritional, Metabolic, Endocrine		

## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

Prof Stephen Atkin

#### Contact details

Michael White Diabetes Centre Hull Royal Infirmary 220 - 236 Analby Road Hull United Kingdom HU3 2RZ

## Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** R0061

# Study information

#### Scientific Title

Effect of atorvastatin on the metabolic syndrome of polycystic ovary syndrome

#### Acronym

PAT

## **Study objectives**

Atorvastatin improves metabolic syndrome and hyperandrogenaemia in patients with polycystic ovary syndrome (PCOS) compared to placebo.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from South Humberside Local Research Ethics Committee on the 5th September 2004 (ref: 04/Q1105/60).

## Study design

A double blind placebo controlled parallel study

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Treatment

## 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 ovary syndrome (PCOS)

#### Interventions

40 patients with polycystic ovary syndrome will be randomised to:

- 1. 20 patients treated with atorvastatin 20 mg
- 2. 20 patients treated placebo

The total duration of the study and follow up is three months.

## Intervention Type

Drug

#### Phase

## Drug/device/biological/vaccine name(s)

Atorvastatin

## Primary outcome measure

Improvement in biochemical hyperandrogenaemia, measured at baseline and after three months.

## Secondary outcome measures

Improvement in insulin resistance, measured at baseline and after three months.

## Overall study start date

13/07/2006

## Completion date

01/05/2008

# **Eligibility**

## Key inclusion criteria

- 1. A diagnosis of PCOS was based on Rotterdam criteria
- 2. Non-classical 21-hydroxylase deficiency, hyperprolactinaemia, and androgen secreting tumours excluded by appropriate tests
- 3. Subjects were advised not to alter their usual dietary and exercise habits
- 4. Females aged 18 40 years

## Participant type(s)

**Patient** 

## Age group

Adult

## Lower age limit

18 Years

## Upper age limit

40 Years

#### Sex

Female

## Target number of participants

40

#### Total final enrolment

40

## Key exclusion criteria

- 1. No concurrent illness
- 2. Patients not wishing to allow disclosure to their GPs
- 3. Patients not on barrier or oral progesterone contraception

## Date of first enrolment

13/07/2006

#### Date of final enrolment

01/05/2008

## Locations

#### Countries of recruitment

England

United Kingdom

Study participating centre Michael White Diabetes Centre

Hull United Kingdom HU3 2RZ

# Sponsor information

#### Organisation

Hull and East Yorkshire Hospital NHS Trust (UK)

## Sponsor details

c/o Mrs Nina Dunham
Research and Development Manager
Research and Development Admin Portacabin
Castle Hill Hospital, Castle Road
Cottingham
Hull
England
United Kingdom
HU16 5JQ

## Sponsor type

Hospital/treatment centre

#### Website

http://www.hey.nhs.uk/

#### **ROR**

https://ror.org/01b11x021

# Funder(s)

## Funder type

University/education

#### Funder Name

University of Hull (UK) - Diabetes Endowment Fund

## **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	01/01/2012		Yes	No
Results article	results	25/06/2019	15/07/2019	Yes	No