

Atorvastatin in polycystic ovary syndrome (PCOS)

Submission date 03/04/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 09/05/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/07/2019	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

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

Protocol serial number
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

Study type(s)

Treatment

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

Not Specified

Drug/device/biological/vaccine name(s)

Atorvastatin

Primary outcome(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

40 years

Sex

Female

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**

United Kingdom

England

Study participating centre

Michael White Diabetes Centre
Hull

United Kingdom
HU3 2RZ

Sponsor information

Organisation

Hull and East Yorkshire Hospital NHS Trust (UK)

ROR

<https://ror.org/01b11x021>

Funder(s)

Funder type

University/education

Funder Name

University of Hull (UK) - Diabetes Endowment Fund

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?
Results article	results	01/01/2012		Yes	No
Results article	results	25/06/2019	15/07/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes