ISRCTN24474824 https://doi.org/10.1186/ISRCTN24474824

Atorvastatin in polycystic ovary syndrome (PCOS)

Submission date	Recruitment status
03/04/2008	No longer recruiting
Registration date	**Overall study status**
09/05/2008	Completed
Last Edited	**Condition category**
15/07/2019	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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

Not Specified

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