Vascular function in polycystic ovary patients after treatment with metformin: its role in polycystic-ovary-syndrome-associated insulin resistance

Submission date	Recruitment status	Prospectively registered
14/02/2006	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
14/02/2006	Completed	Results
Last Edited	Condition category	Individual participant data
05/11/2008	Nutritional, Metabolic, Endocrine	Record updated in last year

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

NTR550

Study information

Scientific Title

Study objectives

The specific aim in the current study is to evaluate if the use of the insulin lowering agent metformin in polycystic ovary syndrome (PCOS) has an effect on micro and macro circulation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised, double blind, placebo controlled, parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Polycystic ovary syndrome (PCOS)

Interventions

Medication:

Patients will be randomised to receive metformin or placebo, two times a day 1000 mg for 6 months.

Vascular measurements:

The measurements will take place at baseline and after metformin therapy. The micro and macro circulation will be measured.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Metformin

Primary outcome measure

Vascular function after metformin therapy compared to vascular function at baseline (micro and macrovascular measurements)

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/01/2006

Completion date

01/10/2007

Eligibility

Key inclusion criteria

- 1. PCOS as judged in early routine patient work-up by three out of the following four criteria:
- 1.1. Oligomenorrhoea (mean length of the menstrual cycle greater than 35 days) or amenorrhoea (based on history of oligomenorrhoea)
- 1.2. Evidence of hyperandrogenism, whether clinical (hirsutism, acne, or male pattern balding) or biochemical (elevated serum androgen level [total testosterone greater than 2 nmol/l, and/or androstedione greater than 9], determined in a period while the patient was not using any medication with potential endocrine influence)
- 1.3. Elevated serum leuteinising hormone (LH) level (greater than 6.5 IU/l), determined at least 2 weeks after the beginning of a menstrual period and 3 weeks before the subsequent menstrual period in the presence of a normal follicle-stimulating hormone (FSH) level (less than 10 IU/l, determined in a period while the patient was not using any medication with potential endocrine influence)
- 1.4. A polycystic ovary morphology (defined by the presence of eight or more subcapsular follicular cysts less than or equal to 10 mm and increased ovarian stroma) by ultrasound performed at our department
- 2. Aged 18 40 years
- 3. One phase combined oral contraceptives with 30 ethinylestradiol (preferred are Microgynon 30®, Stediril 30, Yasmin® and Diane® 35) for at least 3 months but no other medication to avoid hormonal cyclicity and for contraceptive purposes
- 4. Informed consent

Participant type(s)

Patient

Age group

Adult

Lower age limit

Sex

Female

Target number of participants

40

Key exclusion criteria

- 1. Cardiovascular disease (hypertension [greater than 160/90 mmHg], stroke, coronary artery disease, peripheral vascular disease, heart failure)
- 2. Diabetes mellitus (according to American Diabetes Association [ADA] criteria)
- 3. Hypothyroidism, hyperprolactinemia, Cushing's syndrome nonclassical congenital adrenal hyperplasia
- 4. Smoking for the last three months
- 5. Alcohol use greater than 4 units/day
- 6. Pregnancy
- 7. Diseases that influence reproductive hormone status
- 8. Kidney and liver dysfunction or congestive heart failure (which can cause lactic acidosis when taking metformin)

Date of first enrolment

01/01/2006

Date of final enrolment

01/10/2007

Locations

Countries of recruitment

Netherlands

Study participating centre VU University Medical Center Amsterdam

Netherlands 1007 MB

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

Sponsor details

Van der Boechorststraat 7 Amsterdam Netherlands 1081 BT

Sponsor type

Hospital/treatment centre

Website

http://www.vumc.nl

ROR

https://ror.org/00q6h8f30

Funder(s)

Funder type

Industry

Funder Name

Merck (France) - Commercial Unit CardioMetabolic Care

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