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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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)

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Industry

Funder Name
Merck (France) - Commercial Unit CardioMetabolic Care

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration