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The variations in small vascular function and arterial compliance during the menstrual cycle in young healthy women (De cyclus afhankelijke variatie in de microcirculatie bij jonge gezonde ovulerende vrouwen)

Submission date 28/12/2006	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 28/12/2006	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 04/03/2008	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
MCycle

Study objectives
It has been suggested in literature that insulin sensitivity and determinants of the blood pressure vary according to the past ovulation cycle. Since microcirculation plays a large role in the transport and supply of insulin to the muscle fibres, it can be assumed that the microcirculatory function cycle will be dependent on the ovulation cycle. Indeed from literature it has been suggested that this is true, however another group of researchers found no cycle dependent pattern. Moreover in the Vrije University the most unique method has been developed to measure the microcirculation (capillary microscope) and this measuring has never been examined in women in their ovulation cycle. The results of this research are very important for the interpretation of cardiovascular events in women during their ovulation cycle.

Hypothesis:
Microcirculatory function is cycle dependent in healthy ovulating women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics committee

Study design
Non-randomised clinical trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet

Health condition(s) or problem(s) studied
Small vascular function, arterial compliance

Interventions
Microcirculation measured by means of:
1. Microscopic examination of the nail bed (assessment of the refill after temporary occlusion of the finger)
2. Ionthophoresis with acetylcholine (ACH) (endothelium dependent) and sodiumnitroprusside (SNP) (endothelium independent vasodilatation)
3. Blood pressure

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Microcirculatory function measured in three phases of the cycle (early and late follicular, and luteal).

Secondary outcome measures
Blood pressure.

Overall study start date
23/10/2006

Completion date
01/04/2007

Eligibility

Key inclusion criteria
1. Healthy as judged by history and physical examination
2. Regular ovulatory menstrual cycles between 21 - 35 days (proven by biphasic basal temperature curve [BTC] or midluteal progesterone more than 10 nmol/l)
3. Aged 18 to 35 years
4. No medication including oral conceptive or hormonal intra-uterine device (IUD) for at least three months
5. Informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
16

Key exclusion criteria
1. Cardiovascular disease (hypertension [more than 160/90 mmHg], stroke, coronary artery disease, peripheral vascular disease, heart failure)
2. Diabetes mellitus (according to American Diabetes Association [ADA] criteria)
3. Smoking for the last three months
4. Alcohol use more than 4 units/day
5. Pregnancy
6. Diseases that influence reproductive hormone status

Date of first enrolment
23/10/2006

Date of final enrolment
01/04/2007

Locations

Countries of recruitment
Netherlands

Study participating centre
VU University Medical Center
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation
VU University Medical Center (The Netherlands)

Sponsor details
Department of Reproductive Medicine
Postbus 7057
Amsterdam
Netherlands
1007 MB

Sponsor type

Hospital/treatment centre

Website
http://www.vumc.nl/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Research organisation

Funder Name
Institute for Cardiovascular Research of the Vrije University of Amsterdam (ICaR-VU) (The Netherlands)

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