

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/03/2008	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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

Primary study design

Interventional

Study design

Non-randomised clinical trial

Study type(s)

Screening

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. Iontophoresis with acetylcholine (ACH) (endothelium dependent) and sodiumnitroprusside (SNP) (endothelium independent vasodilatation)
3. Blood pressure

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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

Key secondary outcome(s)

Blood pressure.

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 contraceptive or hormonal intra-uterine device (IUD) for at least three months
5. 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 [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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration