

# 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)

<b>Submission date</b> 28/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/12/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/03/2008	<b>Condition category</b> 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

**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. Iontophoresis 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 contraceptive 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