The variations in small vascular wall function during the menstrual cycle in young healthy women.

Published: 12-10-2006
Last updated: 20-05-2024

Is there a cycle-dependent variation of the microvascular function in healthy women.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30179

Source
ToetsingOnline

Brief title
MCycle

Condition

- Other condition

Synonym
nvt

Health condition

het betreft geen aandoening er wordt gekeken naar de vaatfunctie in de cyclus van gezonde vrouwen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: menstrual cycle, microcirculation

Outcome measures

Primary outcome

- cycle dependent microvascular function

- microvascular function is measured in three different ways:

1. capillary refill (with the microscope)

2. endothelial dependent and independent vasodilatation (iontophoresis)

3. insulin dependent vasodilation

4. vasomotion

Secondary outcome

nvt

Study description

Background summary

It is known from the literature that there is a cycle dependent variation of insulin sensitivity in healthy women with an ovulatoiry menstrual cycle. Moreover, insulin sensitivity is assiocated with microvascular function. This suggest that the microvasculair function is also cycle dependent. Williams et al. showed indeed that the microvascular function is different in several stages of the cycle. However, an other study didn't find a cycle dependent variation in the microcirculation. In conclusion there are conflicting data and therefore we designed the current study. Moreover, we use an unique technique developed in the VU medical centre for the assesment of the microcirculatory function. This technique is never done to determine cycle dependent function of the microcirculation. The measurements obtained in the current study are very

important for the intrepretation of cardiovascular data.

Motivation of the used thechniques:
The microscoop is until now only used in the VU medical centre. The big advantage is that it is non-invasief. The iontoforeses is done before by Williams et al and Clifton et al but they had conflicting results. In the current study we will use both techniques to determine if there is a cycle dependent variation in the function of the microcirculation.

Discussion:
Despite of the conflicting results found by Williams et al and Clifton et al (see above), we think that there is a cycle dependent variation in the microcirculatory function. It is known that te insulin sensitivity has a cycle dependent variation in healthy women. Moreover, menopausal women have a lower risk of cardiovascular diseases compared to pre-menopausal women. The explenation for this migth be that pre-menopausal women have an ovulatory cycle, where hormones as estrogen and progestagen are produced. These hormones can influence the vascular function.

Study objective

Is there a cycle-dependent variation of the microvascular function in healthy women.

Study design

Each subject was studied at three points during the menstrual cycle,corresponding to early follicular (EF; day 3 ± 2), late follicular (LF; day 12± 2) and luteal phase (L; day 20 ± 3).
The following measurements are performed
- Microvascular function, i.e. capillary function and iontophoresis (Ach, SNP and insulin)
- Vasomotion
- Blood pressure and heart rate.
- hormones in serum

All subjects will come to the clinic after a 10-h overnight fast. All experiments will be conducted in a quiet, temperature-controlled (23,4 ± 0,4 ºC) room. The first measurement will start after 30 minutes of acclimatization with the subjects in supine position and the investigated hand at heart level.

Study burden and risks

All subjects will come to the clinic after a 10-h overnight fast, sit on a chair 3-4 hours and a venapuntion, which is invasive, have to be performed at each visit (in total three times). The vascular measurement have no risks or

benefits.

Contacts

Public
Academisch Medisch Centrum

de Boelelaan 1117
1091 HV Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

de Boelelaan 1117
1091 HV Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Healthy as judged by history and physical examination
- Regular ovulatory menstrual cycles between 21- 35 days (proven by biphasic BTC or midluteal progesterone > 10 nmol/l)
-18- 35 years
- no medication including oral conceptive or hormonal intra- uterine device (IUD) for at least three months

Exclusion criteria

- Cardiovascular disease (hypertension (>160/90 mmHg), stroke, coronary artery disease,peripheral vascular disease, heart failure)
-Diabetes mellitus (according to ADA criteria)
-Smoking for the last three months
-Alcohol use > 4U/day
-Diseases that influence reproductive hormone status

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL13495.029.06