Anti-oxidative function and composition of high-density-lipoprotein (HDL) in the polycystic ovary syndrome

Published: 23-01-2007
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Primary research questionDo obese PCOS women with reduced insulin sensitivity have HDL particles that have impaired anti-oxidative function in comparison with lean controls with normal insulin sensitivity?Secondary research questionDo obese PCOS...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Endocrine disorders of gonadal function
Study type	Observational invasive

Summary

ID

NL-OMON30680

Source
ToetsingOnline

Brief title
HDL function in PCOS

Condition

- Endocrine disorders of gonadal function
- Ovarian and fallopian tube disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
anti-oxidative HDL function

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anti-oxidative function, high density lipoprotein (HDL), polycystic ovary syndrome (PCOS)

Outcome measures

Primary outcome

Difference in anti-oxidative capacity of HDL between obese PCOS women with reduced insulin sensitivity and lean controls with normal insulin sensitivity.

During oxidation of LDL conjugated dienes are released. Addition of HDL can inhibit the rate of oxidation of LDL; as a consequence less conjugated diens are being released.

In the current study, the difference in conjugated dienes between PCOS and controls will be compared.

NB the anti-oxidative capacity of HDL is measured and expressed independently of the total amount of HDL

Secondary outcome

Difference in composition of HDL between obese PCOS women with reduced insulin sensitivity and lean controls with normal insulin sensitivity.

The composition of HDL particles.

Using ultracentrifugation subfractions of HDL will be isolated:

HDL2a,2b,3a,3b,3c. In these fractions cholesterol, triglycerides, phospholipids

and apolipoproteins will be determined.

The composition of these subfractions will be compared between PCOS and

controls.

As an exploratory parameter the number of endothelial progenitor cells will be

determined in PCOS and in controls.

Study description

Background summary

The polycystic ovary syndrome (PCOS) is characterised by oligo-amenorhea, clinical or biochemical hyperandrogenism and polycystic ovaries on ultrasound. It affects approximately 5 % of premenopausal women. PCOS is associated with insulin resistance, dyslipidemia and abnormal surrogate endpoints for atherosclerosis. Several patterns of dyslipidemia have been described in PCOS; low high density lipoprotein (HDL)-cholesterol is a frequent finding.
HDL particles play an important role in the protection against atherosclerosis, in part by their anti-oxidative capacity. The composition of an HDL particle is a determinant of its function.
Both insulin resistance and low levels of plasma HDL-cholesterol have been associated with impaired anti-oxidative function of HDL particles in predominantly male study populations. No studies of anti-oxidative function of HDL in women have been performed yet.
We hypothesize that PCOS women, who are often obese and insulin resistant, and frequently have low plasma HDL-cholesterol, have impaired (composition and) anti-oxidative function of HDL particles, contributing to their cardiovascular risk.

Endothelial progenitor cells (EPC*s) are involved in endothelial repair. The circulating number of EPC*s is reduced in patients with cardiovascular risk

factors, such as insulin resistance. We hypothesize that PCOS women, who are often insulin resistant, have lower circulating numbers of EPC*s than controls.

Study objective

Primary research question

Do obese PCOS women with reduced insulin sensitivity have HDL particles that have impaired anti-oxidative function in comparison with lean controls with normal insulin sensitivity?

Secondary research question

Do obese PCOS women with reduced insulin sensitivity have a different composition of HDL particles in comparison with lean controls with normal insulin sensitivity?

Explorative research question

Do obese PCOS women with reduced insulin sensitivity have lower numbers of circulating endothelial progenitor cells (EPC*s) in comparison with lean controls with normal insulin sensitivity?

Study design

Case-control

Study burden and risks

Questionaire on cardiovascular risk factors.
Physical examination: height, weight, waist- en hip circumference
Vena punction: max 50 ml blood

Abnormal values for cholesterol, triglycerides or glucose could be found, requiring further investigation and treatment.

Burden and risk are estimated to be low.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Cases: PCOS+, BMI >=27, HOMA >=1.5, 25-40 years of age
Controls: PCOS-, BMI<25, HOMA <1,5 25-40 years of age

Exclusion criteria

Diabetes mellitus
Oral contraceptives
Lipid lowering medication
Pregnancy
Familial hypercholesterolemia
Hypertriglyceridemia
Clinically manifest cardiovascular disease

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2007
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO Date:	23-01-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	06-03-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-06-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-07-2007
Application type:	Amendment

Approved WMO Date:	04-11-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL14897.041.06