Cardiovasculair RisicoprofiEl: IMAGing en reprOductieve aandoeningen

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22481

Source
NTR

Brief title
CREw-IMAGO

Health condition

Reproductive disorders, polycystic ovary syndrome (PCOS), preeclampsia, primary ovarian insufficiency, migraine, venous thromboembolism, cardiovascular disease, risk prediction, coronary computed tomography (CCT)

Reproductieve aandoeningen, polycysteus ovariumsyndroom (PCOS), pre-eclampsie, primaire ovariële insufficiëntie, migraine, veneus tromboembolisme, cardiovasculaire aandoeningen, risico predictie, coronaire computertomografie (CCT)

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Dutch Heart Foundation (In Dutch: Hartstichting)

Intervention

Outcome measures

Primary outcome

• Coronary plaque measured by Coronary Computed Tomography (CCT) including both non-contrast coronary calcium scoring (CACS) and contrast enhanced coronary CT (CCTA).
• Coronary artery stenosis measured by CCTA.
• Biomarkers parameters: plasma CECs, extracellular vesicle protein- and miRNA-concentration, and plasma gene expression profiles in circulating endothelial cells. Numbers, subtype distribution and epigenetic profiles of inflammatory genes of circulating cells.
• Vascular measurements (arterial stiffness)

Secondary outcome

Traditional CVD risk factors (information collected as part of regular cardiovascular screening).

Study description

Background summary

Rationale: Reproductive disorders, including polycystic ovary syndrome (PCOS), primary ovarian insufficiency (POI) and preeclampsia (PE), are associated with an increased risk of cardiovascular diseases (CVD). Similar, migraine and venous thromboembolism (VTE), both common among fertile women, can be considered as female-specific CVD risk factors. Despite recent advances in long term follow-up after reproductive disorders, identifying women who are at risk for CVD remains a challenge. The current CVD risk profile of these young women underestimates future cardiovascular health risks, as the most important contribution in estimating ones risk of CVD is age. The aim of this study is to develop and validate CVD risk evaluation imaging strategies and thereby improve identification of women with (pre)clinical CVD.

Objective: Assessment of coronary artery disease (plaque and stenosis) by low-dose coronary Computed Tomography (CCT), with both non-contrast CT for coronary artery calcium scoring (CACS) and contrast-enhanced CT coronary angiography (CCTA), in patients with a history of a reproductive disorder to improve diagnostic evaluation of CVD risk factors.
Study design: Multicentre, prospective, cohort follow-up study

Study population: Women who experienced 1 or more reproductive disorders (PCOS, POI, PE) and who are at least 45 years of age.

Intervention (if applicable): not applicable.
Main study parameters/endpoints: Assessment of coronary artery disease (plaque and stenosis) by CCT (both CACS and CCTA) in patients with a reproductive disorder to improve

diagnostic evaluation of cardiovascular risk factors.

Study objective

Assessment of coronary artery disease (plaque and stenosis) by low-dose coronary Computed Tomography (CCT), with both non-contrast CT for coronary artery calcium scoring (CACS) and contrast-enhanced CT coronary angiography (CCTA), in patients with a history of a reproductive disorder to improve evaluation of CVD risk factors.

Study design

Planned start date: 1-11-2015
Interim analysis: after 300 CCT's (100 in patients with PE, 100 in patients with PCOS and 100 in patients with POI). If the prevalence of any plaque as seen on CCT is ¡Ý 10% we will continue with performing the remaining 300 CCT¡¯s.

Intervention

- Low-dose coronary Computed Tomography (CCT), with both non-contrast CT for coronary artery calcium scoring (CACS) and contrast-enhanced CT coronary angiography (CCTA).

- Biomarkers

- Non-invasive vascular measurements; pulse wave velocity (PWV)

Contacts

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Eligibility criteria

Inclusion criteria

• Age above 45 years old

• Female

• Capable and willing to provide informed consent.

• Fulfil criteria for diagnosis PE / HELLP syndrome OR fulfil criteria for diagnosis PCOS OR fulfil criteria for diagnosis POI

Exclusion criteria

• Patients with insufficient mastery of Dutch.

• Patients with any serious illness that can compromise study participation.

• Patient who have had a myocardial infarction.

• Patients with high risk for contrast nephropathy (renal function disorder).

• Patients with a history of allergy to iodinated contrast medium.

• Patients who are currently pregnant.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2015
Enrollment:	600
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 47070
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5406
NTR-old	NTR5531
CCMO	NL52772.041.15
OMON	NL-OMON47070

Study results