Cardiovasculair RisicoprofiEl: IMAGing en reprOductieve aandoeningen

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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…

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22481

Bron
NTR

Verkorte titel
CREw-IMAGO

Aandoening

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)

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: Dutch Heart Foundation (In Dutch: Hartstichting)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• 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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

- 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)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2015
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47070
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten