Cardiovascular RiskprofilE: IMaging And Gender-specific disOrders

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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) and additionally a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON47070

Source
ToetsingOnline

Brief title
CREw-IMAGO

Condition

- Other condition
- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Cardiovascular diseases

Health condition

reproductieve aandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Hartstichting

Intervention

Keyword: Cardiovascular riscprofile, Coronary Computed Tomography, Gender-specific disorders

Outcome measures

Primary outcome

Assessment of coronary artery disease (plaque and stenosis) by CCT (both CACS and CCTA) and carotid siphon CT in patients with a reproductive disorder and who are at least 40 years old to improve diagnostic evaluation of cardiovascular risk factors.

Secondary outcome

To compare imaging markers of cardiovascular disease (plaque and stenosis measured by CCT) with standardized vascular screening.

To construct and improve prediction models for the onset of CVD in these patients.

Study description

Background summary

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.

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) and additionally a non-contrast carotid siphon CT, 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 burden and risks

Patients undergoing coronary CT (non-contrast CT for CACS and contrast-enhanced CCTA) and carotid siphon CT will experience an average radiation dose of 3.3-3.4 mSv. This dose is corresponds to the yearly background radiation each person receives in Europe and it is considered low-risk, i.e. a negligible increase in the expected lifetime malignancy risk [Wall 1997, Schussler 2005, Picano 2004]. Other risks of this study are considered negligible. Patients can potentially benefit from information obtained in this study about their current cardiovascular health and expected future risk of cardiovascular events.

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

* Age 40 years or older
* Female
* Capable and willing to provide informed consent.
* Fulfil criteria for diagnosis of hypertensive pregnancy disorders OR fulfil criteria for diagnosis PCOS OR fulfil criteria for diagnosis POI

Exclusion criteria

* Patients with insufficient mastery of Dutch or English.
* 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.;Healthy controls: history of hypertensive pregnancy disorders

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-02-2016
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	07-12-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-06-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-11-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-12-2016

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	09-05-2018
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

ID: 22481
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL52772.041.15
Other	Nog niet bekend
OMON	NL-OMON22481