Cardiac ischemia due to physical or mental stress in women with suspected coronary microvascular dysfunction (CMD)

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to facilitate diagnosis of CMD with the detection of ischemia after stress with 24 hour holter monitoring

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

Summary

ID

NL-OMON42965

Source
ToetsingOnline

Brief title
Cardiac ischemia in CMD

Condition

- Other condition

Synonym
Coronary microvascular dysfunction (microvascular angina pectoris)

Health condition

coronary microvascular dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: door afdeling Cardiologie,Mortara

Intervention

Keyword: 24 hour holter, Cardiac ischemia, Coronary microvascular dysfunction, physical and mental stress

Outcome measures

Primary outcome

Occurrence of cardiac ischemia (defined as >= 1.5 mm ST segment depression in >=3

consecutive cardiac cycles) in the 24 hours following a mental or physical

stress test.

Secondary outcome

- Relation between stress test and cortisol and hs CRP levels

- Time between stress test and occurrence of ischemia

Study description

Background summary

Coronary microvascular dysfunction (CMD) is now acknowledged as a distinct type of ischemic heart disease. Numerous patients, particularly middle aged women, suffer from this chronic, disabling disorder. Unfortunately, the diagnosis is still often missed leading to unnecessary health care utilization with associated costs, diminished quality of life, reduced work participation and, last but not least, a worse cardiovascular prognosis. Several reasons play a role in the under-diagnosis of CMD. Firstly, symptoms are not that typical for angina. They can occur at varying levels of exertion, not during, but after exertion, at rest, or at mental stress. The simplest clue to CMD is to demonstrate cardiac ischemia in the absence of obstructive CAD. Unfortunately, standard ischemia detection tests like an exercise ECG do not perform well in patients with CMD. One possible explanation is that ischemia occurs not during but after the exertion. Another issue is that CMD patients often have symptoms after mental stress which is usually not mimicked in a clinical setting.

Our hypothesis is that 24 hour holter monitoring after physical or mental stress testing can enhance ischemia detection in CMD patients. We thus expect it to facilitate more widespread diagnosis of MCD and prevent a substantial part of patients from having to undergo a more costly and burdensome functional test.

Study objective

to facilitate diagnosis of CMD with the detection of ischemia after stress with 24 hour holter monitoring

Study design

cross-sectional cross-over study

Study burden and risks

The physical and mental stress tests are both stress tests which can be compared with the stress in daily life. During each stress test, participants will get a venous infusion needle and have collect several cortisol measurements with cotton swabs. The Holter monitor, which they have to wear for 24 hours, is small, and comes with a comfortable thin-wire *Leadform* cable that makes monitoring with 10 electrodes practical and without hindering normal daily functioning.The risk of serious adverse events is extremely low, as explained in section 9.2.2. The benefit of the availability of a more facile way to diagnose CMD is substantial. The only way to enhance identification of patients with CMD and distinguish those at increased cardiovascular risk who might benefit from medical therapy, is to enable widespread diagnosis by relatively easy and save tests to detect CMD in daily clinical practice. These tests are not only essential for widespread diagnosis, but also crucial to evaluate novel treatment options.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein-Zuid 10

Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Women 40-65 years, with a clinical diagnosis of CMD; based on symptoms and/or signs of ischemia, the presence of multiple CV risk factors and absence of obstructive coronary artery disease
- CMD with symptoms of ischemia at least twice a week

Exclusion criteria

- Symptoms of ischemia due to obstructive CAD
- An altered diurnal rhythm, such as by working night shifts or insomnia.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	26-07-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-11-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL57384.091.16