

MicroRNA expression profiles of blood in cardiovascular disease

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To establish whether miRNA expression patterns in platelets, monocytes, plasma and endothelial cells differ between subjects with premature CVD and a positive family history of premature CVD as compared to age en sex matched healthy controls.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON35241

Source

ToetsingOnline

Brief title

MiRNAs in CVD

Condition

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

Synonym

coronary artery disease, coronary atherosclerosis

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: biomarkers, microRNAs, premature cardiovascular disease

Outcome measures

Primary outcome

MiRNA expression patterns of thrombocytes, monocytes, plasma and endothelial cells.

Secondary outcome

nvt

Study description

Background summary

Cardiovascular disease (CVD) represents the primary cause of human morbidity and mortality¹, underscoring the need for innovative new diagnostic strategies. Recent studies have identified a powerful role of microRNAs (miRNAs) as highly useful biomarkers. We expect that subjects with premature cardiovascular disease have a specific miRNA expression pattern of their blood as compared to matched healthy controls and that therefore miRNA profiling in blood can be used as novel biomarkers for diagnostic approaches.

Study objective

To establish whether miRNA expression patterns in platelets, monocytes, plasma and endothelial cells differ between subjects with premature CVD and a positive family history of premature CVD as compared to age and sex matched healthy controls.

Study design

Case control study

Intervention

nvt

Study burden and risks

There is no direct benefit or risk for the patients besides the inconvenience of the venapuncture. New strategies to identify subjects at risk for cardiovascular disease are needed. If we can determine miRNA as biomarker in a cohort with premature disease we could possibly use this as a biomarker for CVD in the future. This could then be used for improved individual risk management. Besides the inconvenience of the venapuncture controls have a risk of experiencing side effects of medications. There is a direct benefit for controls, since a general cardiovascular work-up will lead to a cardiovascular risk assessment and might lead to treatment if necessary.

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: men with coronair artery disease under the age of 51 years and a positive family history of premature CVD.

Controls: matched for sex, age and smoking habits

Exclusion criteria

Cases: no cardiovascular event below 51 years

Controles: history or complaints of cardiovascular disease, positive family history of cardiovascular disease, use of medication. Additional exclusion criteria because of carbasaalcalcium and statin administration:

- Allergy for carbasaalcalcium or simvastatin.
- Liver function disorders defined as the upper normal limit of ALAT and ASAT
- CPK above three time upper normal limit
- Renal impairment

Additional exclusion criteria for carbasaalcalcium use:

- Gastric pain or complaints with former use
- Gastric bleeding or perforations
- Ulcers in stomach, esophagus or bowels
- Hypoprothrombinemia

Additional exclusion criteria for statin use:

- Consumption of excessive amount of alcohol defined as 21 units/week
- Hypothyoidism
- Familiar muscle disorders

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting
Start date (anticipated): 02-12-2009
Enrollment: 80
Type: Actual

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Amsterdam UMC

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	NL29313.018.09