

AMBITYON STUDY: the relation between inflammation cells, immune system cells and the development of arteriosclerosis: a study with MRI in young adults.

No registrations found.

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

Summary

ID

NL-OMON25569

Source

Nationaal Trial Register

Brief title

AMBITYON

Health condition

atherosclerosis, MR Imaging, biomarkers, presence, progression, young adults

Sponsors and support

Primary sponsor: University Medical Center Utrecht

Source(s) of monetary or material Support: fund=initiator=sponsor

Intervention

Outcome measures

Primary outcome

(a) presence and (b) rate of change in atherosclerosis over time in young adulthood

(visualized with state-of the-art magnetic resonance imaging techniques) predicted by certain biomarkers of circulating cells and systemic inflammation

Secondary outcome

aortic wall thickness and volume;

presence and number of aortic atherosclerotic plaques (luminal protrusion of > 1 mm in radial thickness);

the extent of aortic atherosclerosis (expressed as % of affected aorta as fraction of total aorta depicted)

Study description

Background summary

Rationale: the relevance of the proposed study lies in clarification of the interrelationship between biomarkers and the presence and (accelerated) progression of atherosclerosis shown with MR Imaging in young adults in order to identify individuals at highest risk of developing clinically manifest atherosclerosis

Objective: the overall objective of this project is to assess the interplay between classical risk factors, plasma markers, markers of activated circulating cells and atherosclerosis burden at MR imaging (expressed as aortic vessel wall thickness and presence of plaques) in the development of atherosclerosis in young adulthood to further elucidate key drivers of clinically manifest atherosclerosis later in life

Study design: a prospective, single center cohort study

Study population: The study population consists of 520 cardiovascular healthy participants between 25-35 years of age drawn from the region of Leidsche Rijn, Utrecht, the Netherlands.

Main study parameters/endpoints: the main study endpoints are twofold:

(1) the levels of markers of circulating cells that predict (a) presence and (b) rate of change in atherosclerosis (visualized with MR Imaging) over time in young adulthood to identify individuals at high risk to develop advanced atherosclerosis over classical cardiovascular risk factors;

(2) aortic wall thickness and presence of aortic plaques found at MR imaging of the thoracic and abdominal aorta

Study objective

the relevance of the proposed study lies in clarification of the interrelationship between biomarkers and the presence and (accelerated) progression of atherosclerosis shown with MR Imaging in young adults in order to identify individuals at highest risk of developing clinically manifest atherosclerosis.

Study design

baseline measurements: completed after 15 months

measurements repeated 3 years after baseline measurements: completed after 51 months

Intervention

Questionnaire: to obtain information regarding age, gender, race, medical history, medication use and lifestyle (smoking, alcohol consumption, dietary intake and social economic status),

Physical examination: measurements of height, weight, waist circumference and blood pressure

Blood sampling: obtained for biochemical analysis including plasma glucose and lipid profile and obtained for biomarker measurements

MR Imaging (with use of gadolinium contrast agent): imaging of thoracic and abdominal aorta, left ventricle function, pulse wave velocity

Contacts

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Eligibility criteria

Inclusion criteria

no medical history of cardiovascular disease and no cardiovascular preventive medication;
between 25-35 years of age;

willing and be able to sign informed consent

Exclusion criteria

subjects with claustrophobia;

subjects with a history of allergic reactions to MR contrast fluids;

subjects with implanted electronic devices (i.e. pacemaker, internal cardioverter-defibrillator, cochlear implants, nerve- and bone stimulators);

subjects with ferromagnetic clips in brain, eyes or lungs;

subjects with a known reduced kidney function ($\text{GFR} < 60 \text{ ml/min}$)

subjects who are 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):	01-01-2014
Enrollment:	575
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 40481
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3992
NTR-old	NTR4164
CCMO	NL44603.041.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40481

Study results

Summary results

N/A