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

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

## Samenvatting

### ID

NL-OMON25569

**Bron**
Nationaal Trial Register

**Verkorte titel**
AMBITYON

**Aandoening**

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

### Ondersteuning

**Primaire sponsor:** University Medical Center Utrecht
**Overige ondersteuning:** fund=initiator=sponsor

### Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

(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

# Toelichting onderzoek

### Achtergrond van het onderzoek

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

### Doel van het onderzoek

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.

### Onderzoeksopzet

baseline measurements: completed after 15 months
measurements repeated 3 years after baseline measurements: completed after 51 months

### Onderzoeksproduct en/of interventie

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

## Contactpersonen

### Publiek

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### Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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 (GFR< 60 ml/min)

subjects who are 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: | 01-01-2014 |
| Aantal proefpersonen: | 575 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40481
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

# Resultaten

**Samenvatting resultaten**
N/A