# Vaatverkalking na niertransplantatie

Gepubliceerd: 22-03-2018 Laatst bijgewerkt: 13-12-2022

The hypothesis addressed in this project is that serum calcification propensity is a predictor of coronary artery calcification progression.

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON21577

**Bron**
NTR

**Verkorte titel**
TransplantLines-CAC

**Aandoening**

Renal transplant recipients; vascular calcification; serum calcification propensity; coronary artery calcification progression.
Niertransplantatie-ontvangers; vasculaire calcificatie; serum verkalkingstendens; CT-calcium score.

### Ondersteuning

**Primaire sponsor:** University Medical Center Groningen
**Overige ondersteuning:** University Medical Center Groningen
Dutch Kidney Foundation

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

To validate serum calcification propensity as a read-out for change in vascular calcification,

measured as CT-based coronary artery calcification score, in renal transplant recipients.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale: Traditional cardiovascular risk factors only partly explain the increased cardiovascular disease (CVD) risk after kidney transplantation. Emerging data suggest that vascular calcification plays a significant role in the aetiology of CVD in this population. The potential of specific interventions to target vascular calcification in renal transplant recipients has barely been explored. Therefore the identification of modifiable key factors driving vascular calcification is needed to provide novel treatment targets able to retard or arrest vascular calcification progression after kidney transplantation. Studying vascular calcification is limited by the drawback that most current techniques assess prevalent calcification, requiring expensive, repeated measurements with a considerable interval. Importantly, a serum test was recently developed that quantifies the tendency to develop new vascular calcifications in contrast to prevalent calcifications. The hypothesis addressed in this project is that serum calcification propensity is a predictor of coronary artery calcification progression.
Objective: The main objective is to validate serum calcification propensity as a read-out for vascular calcification and the secondary objective is to identify determinants of vascular calcification (progression).

Study design: A prospective, single-centre, longitudinal, observational study. This study will be performed in the context of the TransplantLines biobanking project.

Study population: Renal transplant recipients, 6-12 months post kidney transplantation, of ≥18 years who participate in TransplantLines and have a renal function (eGFR) of > 30 ml/min/1.73m2, are eligible for this study. Exclusion criteria are: life-expectancy < 2 years, active malignancy (exception treated basal cell or squamous cell carcinoma), and known pregnancy. We aim to include 250 participants.

Intervention (if applicable): All participants will undergo ultra-low-dose CT scanning and pulse wave velocity measurement in addition to the TransplantLines protocol.

Main study parameters/endpoints: The main study parameter is the association between baseline serum calcification propensity and the relative change in the CAC score over a two-year period.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Ultra-low-dose CT scans of the heart will be performed. The total study related radiation dose as calculated by the radiation expert will be 1.2 mSv. These dose ranges fit very well within the radiation dose limits for population imaging as defined by the Gezondheidsraad. Radiodiagnostic technicians will perform and radiologists will evaluate the CT scans. There are no adverse events expected during the collection of the CT scans.

Zie ook de website https://www.umcg.nl/NL/UMCG/Afdelingen/Transplantatiecentrum/onderzoek/transplantlines/Paginas/default.aspx

**Doel van het onderzoek**

The hypothesis addressed in this project is that serum calcification propensity is a predictor of coronary artery calcification progression.

**Onderzoeksopzet**

Follow-up of two years

**Onderzoeksproduct en/of interventie**

All participants will undergo ultra-low-dose CT scanning and pulse wave velocity measurement in addition to the TransplantLines protocol.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

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

1. Age ≥18 years

2. Male and female renal transplant recipients

3. Participant of TransplantLines

4. 6-12 months post kidney transplantation

5. eGFR > 30 ml/min/1.73m2

6. Signed informed consent

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

1. Life-expectancy < 2 years

2. Active malignancy; exception treated basal cell or squamous cell carcinoma

3. Known pregnancy

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 16-04-2018 |
| Aantal proefpersonen: | 250 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 22-03-2018 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

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

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL6910 |
| NTR-old | NTR7105 |
| Ander register | METc UMCG : 2017/671 |

# Resultaten