Vaatverkalking na niertransplantatie

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21577

Source
NTR

Brief title
TransplantLines-CAC

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen
Dutch Kidney Foundation

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Identify determinants of vascular calcification (progression) in renal transplant recipients; classical cardiovascular risk factors, mineral metabolism factors, calcification inhibitors and dietary factors.

Study description

Background summary

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

Study objective

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

Study design

Follow-up of two years

Intervention

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

Contacts

Public
N.T. Linde, van der
[default]
The Netherlands
(050) 361 97 10
Scientific
N.T. Linde, van der
[default]
The Netherlands
(050) 361 97 10

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

1. Life-expectancy < 2 years

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

3. Known pregnancy

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-04-2018
Enrollment:	250

Type:	Anticipated

Ethics review

Positive opinion Date:	22-03-2018
Application type:	First submission

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
NTR-new	NL6910
NTR-old	NTR7105
Other	METc UMCG : 2017/671

Study results