

Microcirculatory perfusion in living kidney donors.

Gepubliceerd: 06-03-2019 Laatste bijgewerkt: 19-03-2025

Hypothesis: We hypothesize that perfused and total micro vessel density in living kidney donors will be decreased after kidney donation.

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

Samenvatting

ID

NL-OMON20333

Bron

NTR

Verkorte titel

microLINKED

Aandoening

Not applicable

Ondersteuning

Primaire sponsor: Not applicable

Overige ondersteuning: Nierstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary outcome: Mean perfused vessel density difference between different time points will be analysed by using paired T-tests.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Recent studies comparing equally healthy controls with donors suggest that living kidney donation is associated with increased risk of developing cardiovascular disease. However, mechanisms underlying this possible association remain unknown. In this study, we aim to investigate whether microcirculatory perfusion becomes compromised after unilateral nephrectomy in living donors in order to get more insight in the possible mechanism behind the development of CVD after kidney donation.

Objective:

To study microcirculatory perfusion in living kidney donors before and after donation.

Study design:

Single center, prospective observational study

Study population:

Living kidney donors > 18 years of age.

Intervention (if applicable):

Not applicable

Main study parameters/endpoints:

The primary outcome is to study the difference in perfused and total vessel density before and after unilateral nephrectomy in living kidney donors.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

There will be no benefit for patients participating in this study. The use of the USB3 MicroScan imaging camera is a non-invasive sublingually measurement technique which exposes patients to minimal risk and burden.

Doel van het onderzoek

Hypothesis: We hypothesize that perfused and total micro vessel density in living kidney donors will be decreased after kidney donation.

Onderzoeksopzet

Time points: 1 day before donation and 3 weeks after donation.

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria: In order to be eligible to participate in this study, a subject must meet all of the following criteria:

- Age > 18
- Living kidney donors
- Provision of written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria:

- If candidate cannot understand Dutch or English.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	25-06-2018
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

Data will be handled coded and confidentially. Mean overall result will be shared to all participants (no individual subject information will be shared). Only the Principal Investigator will have access to the individual patient data and the subject identification code list. These data are secured and protected by a password in line with the General Data Protection Regulation (GDPR) of the Amsterdam UMC, location VUmc.

Ethische beoordeling

Positief advies	
Datum:	06-03-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46695
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7566
CCMO	NL65200.029.18
OMON	NL-OMON46695

Resultaten