Microcirculatory perfusion in living kidney donors.

No registrations found.

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

Summary

ID

NL-OMON20333

Source
NTR

Brief title
microLINKED

Health condition

Not applicable

Sponsors and support

Primary sponsor: Not applicable
Source(s) of monetary or material Support: Nierstichting

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Secondary outcome: Mean total vessel density difference between different time points will analysed by using paired T-tests.

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Exclusion criteria:

- If candidate cannot understand Dutch or English.

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:	Recruiting
Start date (anticipated):	25-06-2018
Enrollment:	20
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
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.

Ethics review

Positive opinion

Date:	06-03-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 46695
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results