

# microcirculatory perfusion in living kidney donors

Published: 23-05-2018

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Completed
<b>Health condition type</b>	Heart failures
<b>Study type</b>	Observational invasive

## Summary

### ID

NL-OMON46695

### Source

ToetsingOnline

### Brief title

microLINKED

### Condition

- Heart failures

### Synonym

cardiovascular disease

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

### Intervention

**Keyword:** cardiovascular disease, living kidney donors, microcirculation

## Outcome measures

### Primary outcome

The main endpoint is to assess if perfused vessel density (PVD) in living kidney donors will be decreased after donation

### Secondary outcome

- 1) total vessel density (TVD)
- 2) eGFR
- 3) serum RAAS markers (aldosterone/renine ratio), FGF-23, insulin resistance markers (HOMA-IR), inflammation markers (hs-CRP and IL-6) levels

## Study description

### Background summary

Recent studies comparing equally healthy controls with donors suggest that living kidney donation is associated with increased risk of developing cardiovascular disease (CVD). 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.

### Study objective

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

### Study design

- Single center, prospective observational study
- Sublingual microcirculation measurements take place one day before surgery and two weeks after surgery.
  - Blood sampling to determine levels of serum RAAS markers (aldosterone/renine ratio), FGF-23, insulin resistance markers (HOMA-IR) and inflammation markers

(hs-CRP and IL-6)

### **Study burden and risks**

Imaging of the sublingual microcirculation is a non-invasive technique, with minimal burden for the patient. Therefore, risks associated with participation are negligible.

## **Contacts**

### **Public**

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### **Scientific**

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## **Trial sites**

### **Listed location countries**

Netherlands

## **Eligibility criteria**

### **Age**

Adults (18-64 years)  
Elderly (65 years and older)

### **Inclusion criteria**

Age > 18  
Living kidney donors

Provision of written informed consent

## Exclusion criteria

If candidate cannot understand Dutch or English.

## Study design

### Design

**Study type:** Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Completed

Start date (anticipated): 25-06-2018

Enrollment: 20

Type: Actual

## Ethics review

Approved WMO

Date: 23-05-2018

Application type: First submission

Review commission: METC Amsterdam UMC

## Study registrations

**Followed up by the following (possibly more current) registration**

No registrations found.

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

ID: 20333

Source: NTR

Title:

## In other registers

Register	ID
CCMO	NL65200.029.18
OMON	NL-OMON20333

## Study results

Date completed: 19-06-2019

### Summary results

Trial ended prematurely