Treatment transitions in uremia: A survey on the effects of transplantation on cardiovascular and nutritional state, and physical activity

Published: 14-08-2013
Last updated: 24-04-2024

The main objective is to study the effect of renal transplantation with a living donor on selected cardiovascular, nutritional and activity parameters in both recipients as well as living donors.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON41560

Source
ToetsingOnline

Brief title
Transitions in uremia ktx

Condition

- Nephropathies

Synonym
kidney transplantation

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Fresenius FMC,via een unrestricted grant van Fresenius MC. Deze firma is geen opdrachtgever en heeft geen invloed op de uitvoering en verwerking van het onderzoek.

Intervention

Keyword: Overhydration, Physical Activity, Pulse wave velocity, Transplantation

Outcome measures

Primary outcome

Overhydration; bio-impedance

Pulse wave velocity

Body composition; bio-impedance

Physical activity; sensewear armband

Secondary outcome

capillary microscopy

handgriph strength

laboratory parameters

skin autofluorescense

Study description

Background summary

In the life of patients with end-stage renal disease, two major events are the start of dialysis and, if applicable, renal transplantation, which is seen as the best possible solution. It is likely that renal transplantation has major beneficial effects on cardiovascular and nutritional parameters, as well as volume status and physical activity levels. Whereas many cross-sectional studies have addressed these parameters in renal transplant patients, few studies have focused on the longitudinal effects of renal transplantation. This study may be of relevance in assessing the reversibility of uremic complications by kidney transplantation.
Also less information is available on the effects of kidney donation from a

living donor. Studies which were conducted on cardiovascular parameters and body composition parameters are often of retrospective design. For nutritional parameters and physical activity less is known. This study can provide more information concerning the recovery of living kidney donors in a longitudinal setting and show how soon donors are recovered until prédonation levels.

Study objective

The main objective is to study the effect of renal transplantation with a living donor on selected cardiovascular, nutritional and activity parameters in both recipients as well as living donors.

Study design

This is a longitudinal observational study, with a follow-up duration of twelve months.
The study parameters will be assessed before transplantation during a visit at the pre-transplantation clinic, at the day before renal transplantation, day 1 after renal transplantation, and at 1 week, 1 months, 3 months, 6 months and 12 months after renal transplantation (in total 8 times).
Controls (donors) will be measured three times; before donation, 3 months after donation and 12 months after donation.

Study burden and risks

In this study, only non-invasive techniques will be performed, which pose a minimal burden to the patient. Blood sampling will coincide as much as possible with regular blood takings for clinical purposes. The study will not have direct benefit for the participants. The study can only be performed within this specific patient group.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P Debyelaan 25
Maastricht 6229 HX

NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age > or equal to 18 years.
Ability to provide written informed consent.
Patients who will receive a kidney transplant from a living kidney donor.

Exclusion criteria

Patients:
Inability to provide informed consent.
For bioimpedance measurements: presence of ICD or pacemaker. There are no restrictions for other measurements in these patients.;Controls:
Hypertension (blood pressure higher than 170 mm/Hg systolic and higher than 100 mm/Hg diastolic during the screening)
Diabetes mellitus
Active malignancies/infections;Donors are already screened for these exclusion criteria at the pre-transplantation clinic to get approval for kidney donation.

Study design

Design

Study type: Observational invasive

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-10-2013
Enrollment:	44
Type:	Actual

Ethics review

Approved WMO

Date:	14-08-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	05-02-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	16-04-2015
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL43381.068.13