

The effects of kidney transplantation on circadian rhythm. Focus on sleep and cardiometabolic risks.

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Primary Objective: - What influence has kidney transplantation on (recovery of) melatonin production? Secondary Objective(s): - Is recovery of melatonin rhythm after kidney transplantation related to improvement of other circadian rhythms, e.g. body...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disorders and disturbances
Study type	Observational invasive

Summary

ID

NL-OMON34859

Source

ToetsingOnline

Brief title

Circadian Rhythm In Kidney Transplantation -01 (CRIKT-01)

Condition

- Sleep disorders and disturbances
- Renal disorders (excl nephropathies)

Synonym

circadian rhythm, kidney transplantation

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Personeel: de uitvoerend onderzoeker wordt

gefinancierd door Meander Medisch Centrum te Amersfoort. Deze studie zal onderdeel uitmaken van combinatie opleiding tot ziekenhuisapotheker + promotieonderzoek. Materiaalkosten voor deze studie komen t.l.v. Divisie 1 beheer BV - Nefrologie;VUmc

Intervention

Keyword: circadian rhythm, kidney transplantation, melatonin, sleep

Outcome measures

Primary outcome

Primary endpoint: recurrence of the 'dim light melatonin onset (DLMO)' after kidney transplantation. Definition of the DLMO: melatonin concentration peak >4 pg/ml in saliva, between 7 and 12 pm.

Secondary outcome

Secondary outcomes are: changes in objective and subjective sleep parameters, changes in circadian body temperature, ambulant blood pressure profile, cardiometabolic parameters and quality of life.

Study description

Background summary

Previous research has revealed that sleep and melatonin rhythm are often disturbed in patients with chronic renal failure. In a pilot project (n=7) we have shown that melatonin rhythm had improved in some patients after kidney transplantation compared to when they were still on hemodialysis. However, in others it had not improved. This led to the design of this study in which we will observe a larger group of end-stage-renal-failure patients that will receive a kidney transplant and their kidney donors to objectify the effect of kidney transplantation on sleep, melatonin production, body temperature and blood pressure. Possible correlations between changes in melatonin production and other effects such as blood pressure and sleep will be addressed.

Study objective

Primary Objective:

- What influence has kidney transplantation on (recovery of) melatonin production?

Secondary Objective(s):

- Is recovery of melatonin rhythm after kidney transplantation related to improvement of other circadian rhythms, e.g. body temperature and ambulant blood pressure?
- Is recovery of melatonin rhythm after kidney transplantation related to improvement of cardiovascular intermediate endpoints, e.g. blood pressure dipping profile, IL-6 and hsCRP levels?
- Is recovery of melatonin rhythm after kidney transplantation related to improvement in sleep-wake rhythm and quality of life?

Study design

longitudinal observational study

Study burden and risks

Measurements in kidney recipients take place at 1 month before transplantation, 2 weeks and 3 months after transplantation.

Measurements in kidney donors take place at 1 month before transplantation and 3 months after transplantation.

Kidney recipients:

- 3x objective sleep registration by actigraphy
- 3x saliva sampling for measuring melatonin curves
- 3x sleep questionnaire (Epworth Sleepiness Scale)
- 3x quality of life questionnaire (MOS-SF36)
- 2x 24-hr blood pressure measurement
- 3x venipuncture
- 2x body temperature measurement

Kidney donors:

- 2x objective sleep registration by actigraphy
- 2x saliva sampling for measuring melatonin curves
- 2x sleep questionnaire (Epworth Sleepiness Scale)
- 2x quality of life questionnaire (MOS-SF36)
- 2x 24-hr blood pressure measurement
- 2x venipuncture
- 2x body temperature measurement

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Kidney recipients:

- aged 18-85 yr
- living donor transplantation
- good understanding of dutch language
- informed consent;

Kidney donors:

- aged 18-85 yr
- good understanding of dutch language
- informed consent

Exclusion criteria

- use of hypnotics/melatonin during the study
- relevant co-morbidity that interferes with participation in the study (e.g. heart failure NYHA class IV, instable AP, pulmonary, psychiatric, neurologic, blindness)

- documented sleep apnea
- alcohol / drug abuse

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 27-04-2011

Enrollment: 60

Type: Actual

Ethics review

Approved WMO

Date: 11-01-2011

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

No registrations found.

In other registers

Register	ID
CCMO	NL31617.029.10