

Circadian Rhythm in Kidney Transplantation.

No registrations found.

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

Summary

ID

NL-OMON22422

Source

NTR

Brief title

CRIKT-01

Health condition

kidney transplantation
circadian rhythm
sleep disturbances
ambulatory blood pressure

Dutch: niertransplantatie, circadiane ritmiek, slaapstoornissen, 24u-bloeddruk

Sponsors and support

Primary sponsor: VU University Medical Centre, Amsterdam, The Netherlands

Meander Medical Centre, Amersfoort, The Netherlands

Source(s) of monetary or material Support: VU University Medical Centre, Amsterdam, The Netherlands

Meander Medical Centre, Amersfoort, The Netherlands

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Change in subjective and objective sleep parameters;
2. Circadian body temperature;
3. Ambulant blood pressure profile;
4. Quality of life.

Study description

Background summary

Monocentre study, VU University Medical Centre, Amersfoort, The Netherlands.

Study objective

Increasing kidney function by kidney transplantation might improve the circadian rhythms of melatonin concentration, sleep and 24-hour blood pressure profile.

Study design

Kidney recipients:

1. DLMO (salivary melatonin concentration), ESS (subjective sleep), actigraphy (objective sleep): measured at baseline, 14 days after Tx and 3 months after Tx;
2. MOS-SF36, 24-hour body temperature and 24-hour ambulatory blood pressure measurement are taken at baseline and 3 months after Tx.

Kidney donors:

1. DLMO (salivary melatonin concentration), ESS (subjective sleep), actigraphy (objective sleep), MOS-SF36, 24-hour body temperature and 24-hour ambulatory blood pressure measurement are taken at baseline and 3 months after Tx.

Intervention

The course of the circadian rhythms of melatonin, ambulatory blood pressure, body temperature and sleep are measured in kidney transplant recipients and their living kidney donors before and after kidney transplantation (Tx). A sleep questionnaire (Epworth Sleepiness Scale, ESS) and quality of life questionnaire (MOS-SF36) are taken at baseline and after transplantation.

Contacts

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Eligibility criteria

Inclusion criteria

Kidney recipients:

1. Aged 18-85 yr, both male and female;
2. Living donor transplantation;

3. Good understanding of dutch language;
4. Informed consent.

Kidney donors:

1. Aged 18-85 yr, both male and female;
2. Good understanding of dutch language;
3. Informed consent.

Exclusion criteria

Both recipients and donors:

1. Use of hypnotics/melatonin during study measurements;
2. Relevant co-morbidity that interferes with participation in the study according to the investigators (e.g. heart failure NYHA class IV, instable AP, pulmonary, psychiatric, neurologic, blindness);
3. Documented sleep apnea;
4. Alcohol / drug abuse.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	27-04-2011
Enrollment:	70
Type:	Actual

Ethics review

Positive opinion	
Date:	12-07-2011
Application type:	First submission

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
NTR-new	NL2833
NTR-old	NTR2974
Other	METc VUmc // ABR number : 210/253 // NL31617.029.10;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A