

Circadian Rhythm in Kidney Transplantation.

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22422

Bron

Nationaal Trial Register

Verkorte titel

CRIKT-01

Aandoening

kidney transplantation
circadian rhythm
sleep disturbances
ambulatory blood pressure

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

Ondersteuning

Primaire sponsor: VU University Medical Centre, Amsterdam, The Netherlands
Meander Medical Centre, Amersfoort, The Netherlands

Overige ondersteuning: VU University Medical Centre, Amsterdam, The Netherlands
Meander Medical Centre, Amersfoort, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	27-04-2011
Aantal proefpersonen:	70

Type:

Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:

12-07-2011

Soort:

Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A