Effects of light therapy on sleep, melatonin rhythm and mood in hemodialysis

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Measuring the effects of light therapy during hemodialysis on objective en subjective sleep parameters, sleepiness during dialysis, mood and melatonin rhythm. De results of this pilot study can be used to design a larger study on light therapy in...

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

Summary

ID

NL-OMON34818

Source
ToetsingOnline

Brief title
Study on Hemodialysis: IlluminatioN Effects (SHINE)

Condition

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

Synonym
sleep disturbances, sleep wake rhythm

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: eigen middelen ziekenhuisapotheek

Intervention

Keyword: hemodialysis, light therapy, mood, sleep

Outcome measures

Primary outcome

Improvement of van objective sleep parameters, measured by actigraphy.

Secondary outcome

Changes in subjective sleep, melatonin rhythm, sleepiness during hemodialysis

and mood

Study description

Background summary

Previous research has shown that many patients with chronic kidney disease suffer from sleep disturbances. A possible explanation can be found in the disturbed or insufficient melatonin secretion in patients with chronic kidney disease. Previously, we have studied the effects of two different interventions on improvement of sleep in hemodialysis patients: switch from daytime hemodialysis to nocturnal hemodialysis and administration of exogenous melatonin. Both interventions led to an improvement of objective and subjective sleep parameters and a rise in melatonin secretion. In this pilot study, we propose a third intervention to improve sleep disturbances and mood of hemodialysis patients: light therapy. Light is one of the strongest cues for the biological clock to synchronize with the environment. We hypothesize that exposure to light therapy will reduce sleepiness during dialysis and thereby improves the circadian sleep/wake rhythm.

Study objective

Measuring the effects of light therapy during hemodialysis on objective en subjective sleep parameters, sleepiness during dialysis, mood and melatonin rhythm. De results of this pilot study can be used to design a larger study on light therapy in patient with chronic kidney disease.

Study design

intervention trial, cross over model, open label

Intervention

All subjects will be exposed to 3 weeks of light therapy during hemodialysis. The effects will be compared to a 3-week-period without light therapy during hemodialysis in the same patient (cross over model)

Study burden and risks

Measurements will take place at 3 moments during the study: at start, end of light period and end of dark period.
Measurements are non-invasive.
Possible benefit of the participants includes improvement of sleep, mood and melatonin rhythm.
List of participant activities:
- objective sleep measurement (actigraphy): 3 x 5 days
- melatonin curve in saliva: collection of 3 x 5 saliva samples at 7, 9, 11 pm and 0 and 7 am
- morningness-eveningness questionnaire: 1x
- Epworth sleepiness scale: 3x
- Mood questionnaire (HAMD6-questionnaire): 3x
- Karolinska sleepiness scale: 6x

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- hemodialysis patient
- age 18-85 years
- good understanding and knowledge of dutch language
- informed consent
- subjective sleep disturbance
- intermediate score on morningness-eveningness questionnaire

Exclusion criteria

- severe co-morbidity (neurological, psychiatric, eye diseases, e.g.blindness) that, according to the investigator, impedes the study
- use of melatonin/hypnotics (wash out period before inclusion at least 1 week)
- use of drugs that induce photosensitivity
- active daily programme (job or study) during the day
- jet lag or >1 time zone in the last week

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-03-2010
Enrollment:	16
Type:	Actual

Medical products/devices used

Generic name:	Philips EnergyLight
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-03-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT01064544
CCMO	NL31080.100.09