Double blind placebo controlled study on the efficacy of melatonin on sleep parameters and quality of life in hemodialysis patients

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Does melatonin by improving sleep parameters improve quality of life of hemodialysis patients?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON30731

Source
ToetsingOnline

Brief title
Melody

Condition

- Heart failures
- Sleep disturbances (incl subtypes)
- Renal disorders (excl nephropathies)

Synonym
Dialysis, kidney function replacement therapy

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: Nierstichting

Intervention

Keyword: Heart failure, Melatonin, Quality of life, Sleep

Outcome measures

Primary outcome

1) improvement of vitality (dimension quality of life) by 15 points (RAND SF 36)

2) improvement general health by 15 points (dimension quality of life, RAND SF

36)

Secondary outcome

1) Change in biochemical parameters

2) Change in ProBNP

3) Change in nutritonal status

4) Change in use of medication

5) Change in preload

Study description

Background summary

Sleep problems can lead to a bad quality of life and a raise of morbidity, also in dialysis patients. Sleep problems can be caused by a disturbance of circadian rhythms in our body. For a good regulation of these circadian rhythms a uniform external synchronisation is necessary. This is the synchronisation of the biological clock of our body by light and other influences. In case of a disturbance of the external synchronisation, due to for example naps during the day or wake periods at night, internal rhythms can be unlinked. As a result a weakened melatonin rhythm and a problematic sleep-wake cycle can be observed. Most dialysis patients have sleep problems. Their sleep latency is prolonged.

They often take a nap during the day and their sleep efficiency is poor. There has only been one study on the melatonin rhythm of dialysis patients. The conclusion of this study was that the melatonin rhythm of dialysis patients is weakened and disturbed, probably caused by renal insufficiency. In this study no link was made between melatonin rhythm and the nature and severity of possible sleep problems. In different studies with non-dialysis patients and a disturbed melatonin rhythm, exogenous melatonin at the right time leads to a recovery of the normal rhythm and the normal biological clock and a better quality of life.
The aim is to improve quality of life of hemodialysis patients with a placebo-controlled study with melatonin to investigate if exogenous melatonin can improve sleep problems and on the longer term improve quality of life (and secundary morbidity) of dialysis patients.

Study objective

Does melatonin by improving sleep parameters improve quality of life of hemodialysis patients?

Study design

Placebo-controlled, double-blind, randomized trial

Intervention

melatonin 3 mg once daily (or placebo)

Study burden and risks

Benefit: Better sleep, better quality of life and possible decreased comorbidity

Burden: wearing actometer (watch), chewing swabs (melatonin in saliva)
Answering questionnaires, 24 hour blood pressure measurement, extra blood withdrawal

Contacts

Public
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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1) Informed Consent
2) Man/Women between 18 and 85 years
3) Understanding and knowledge of the dutch language
4) End Stage Renal Disease, stable chronic hemodialysis > 3 months
5) SpKt/V(total) > 1,2 pro dialysis
6) Validated actometer shows that sleep efficiency < 90% or sleep latency > 15 minutes or fragmentation index > 25 points

Exclusion criteria

1) Known major illness, which interferes with patient's participation in the study (according to the investigator) or which results in a probable patient's survival of less than 1 year.
2) Instable angina pectoris, heart failure NYHA class IV
3) Pregnancy
4) Current use of melatonin of known allergy of melatonin
5) Participation in other medication/drug research within a month before inclusion
6)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-05-2007
Enrollment:	68
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Bio-Melatonin 3 mg
Generic name:	Melatonin

Ethics review

Approved WMO Date:	13-11-2006
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	04-01-2007
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United

	(Nieuwegein)
Approved WMO Date:	06-07-2007
Application type:	Amendment
Approved WMO Date:	27-08-2007
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-07-2008
Application type:	Amendment
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
Other	aanmelding clinicaltrials.gov
EudraCT	EUCTR2006-005719-89-NL
CCMO	NL12440.100.06