

# Melatonin Pharmacokinetics in Dialysis Patients

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Primary aim: Does melatonin accumulate in hemodialysis patients after a treatment period with exogenous melatonin for at least 12 weeks ?Secondary aim:Will 7 days be enough to erase the accumulated melatonin?What are the pharmacokinetics of...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Renal disorders (excl nephropathies)
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON40235

### Source

ToetsingOnline

### Brief title

Melatonin kinetics in dialysis / MEKDIP

### Condition

- Renal disorders (excl nephropathies)

### Synonym

Hemodialyse

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Meander Medisch Centrum

**Source(s) of monetary or material Support:** Ziekenhuisapotheek Meander Medisch Centrum

## Intervention

**Keyword:** Hemodialysis, Melatonin, Pharmacokinetics

## Outcome measures

### Primary outcome

Melatonin concentration measured in saliva versus time of day during 24 hours.

### Secondary outcome

Melatonin concentration measured in saliva, calculating area under the curve

Change in baseline melatonin concentration (comparing melatonin concentration

t=15:00 of 3 different days)

Objective sleep parameters using actometer and the relation to melatonin kinetics.

Subjective sleep score using ESS questionnaire and chronotype and the relation to melatonin kinetics.

## Study description

### Background summary

In previous research we showed that as the kidney function deteriorates, the nocturnal melatonin secretion decreases. In hemodialysis patients the nocturnal melatonin surge is frequently absent. Supplementation of melatonin in hemodialysis patients with sleep problems indeed raises the melatonin concentration, but the favourable impact on improvement of sleep is only present for a few weeks or months. Because melatonin is partly cleared renally and it is important for the impact on sleep that the difference between day concentration and night concentration is sufficiently large, we presume that

accumulation of melatonin possibly is the cause for the decreasing clinical effect

## **Study objective**

Primary aim: Does melatonin accumulate in hemodialysis patients after a treatment period with exogenous melatonin for at least 12 weeks ?

Secondary aim:

Will 7 days be enough to erase the accumulated melatonin?

What are the pharmacokinetics of melatonin after a treatment period of at least 12 weeks of exogenous melatonin in hemodialysis patients?

## **Study design**

It concerns pharmacokinetic research in patients who get melatonin in standard care. I.

## **Intervention**

Discontinuation of melatonin for 7 days

## **Study burden and risks**

The patients undergo:

analysis of 6 melatonin in saliva: 3 x 6 saliva swaps at home are collected at 19:00, 21:00, 23:00, 01:00 and 07:00 and 15:00 (day 1, day 3 and day 7 after stop), after a dialysis.

Fill in of a subjective sleep questionnaire (Epworth Sleepiness Scale: 10 short questions): at baseline, after 6 weeks melatonin use and 7 days after stopping melatonin. Fill in a questionnaire to determine the chronotype (morning/evening) at baseline. (VOA: 7 short questions)

## **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**

Hemodialysis patients

Age: 18-85 years

Informed consent

Good knowledge of dutch language

Melatonin use for at least 12 weeks

### **Exclusion criteria**

Severe comorbidity such as heart failure class IV, instable AP, pulmonal, psychiatric or neurologic disease

Blindness

Nocturnal dialysis

Documented sleep apnea

Alcohol or drug abuse

Use of hypnotics such as benzodiazepines

## **Study design**

## Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

## Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 20-02-2014

Enrollment: 8

Type: Actual

## Ethics review

Approved WMO

Date: 24-09-2013

Application type: First submission

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 19-12-2014

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
CCMO	NL43933.100.13