Circadian rhythm of erythropoietin and melatonin in patients with various degrees of renal insufficiency, Part one

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Primary objective: Is there a similar circadian rhythm of epo and melatonin in patients with the same degrees of renal insufficiency?Primary Objective: Is there a similar circadian rhythm of epo and melatonin in patients with various degree of renal...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Renal disorders (excl nephropathies)
Study type	Observational invasive

Summary

ID

NL-OMON31373

Source
ToetsingOnline

Brief title
Circadian Rhythm of Erythropoietin and Melatonin in renal disease /CREAM 1

Condition

- Renal disorders (excl nephropathies)

Synonym
biological rhythm, circadian processes

Research involving
Human

Sponsors and support

Primary sponsor: Meander Medisch Centrum
Source(s) of monetary or material Support: stichting bijstand van het ziekenhuis

Intervention

Keyword: Biological rhythm, Erythropoietin, Melatonin, Renal disease

Outcome measures

Primary outcome

Analysis of the existence of a circadian rhythm in patients with a normal renal

function and in patients with variable degrees of renal insufficiency

Secondary outcome

not applicable

Study description

Background summary

Many biological processes in our body follow a 24 hours (= circadian rhythm), for example the sleep wake rhythm. This study focuses on the circadian rhythm and the disruption of these rhythm due to renal failure. Erythropoietin (epo) and melatonin are analyzed in serum and saliva. Dependent on the results of this study part two of the CREAM can be started, in which variable times of adminstration of epo could lead to more efficient use of epo (less costs and more patient friendly). This research is a novelty in its kind.

Study objective

Primary objective: Is there a similar circadian rhythm of epo and melatonin in patients with the same degrees of renal insufficiency?

Primary Objective: Is there a similar circadian rhythm of epo and melatonin in patients with various degree of renal insufficiency compared to patients with a normal renal function?

Secondary Objective: Is there a similar circadian rhythm of cortisol and IGF in patients with the same degrees of renal insufficiency??

Secondary Objective: Is there a similar circadian rhythm of cortisol and IGF in patients with various degree of renal insufficiency compared to patients with a normal renal function?

Study design

Comparative study in 4 groups with various degrees of renal insufficiency, duration for each patient 24 hrs. Total duration of study 6 months, patients admitted to the hospital (on nursing ward)

Study burden and risks

Better knowledge of the circadian rhythm in renal insufficiency. This could lead to a more efficient administration of erythropoietin and melatonin in the future.
Extent of burden is 1 venapunction for placement of infusion needle, the withdrawal of 12 times 5 ml blood in 24 hrs, 12 times 1 minute chewing on cotton plug and measurement of body temperature (12 times)

Contacts

Public
Meander Medisch Centrum

Postbus 1502
3800 BM Amersfoort
Nederland
Scientific
Meander Medisch Centrum

Postbus 1502
3800 BM Amersfoort
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

o Patient with various degrees of renal insufficiency, creatinin clearance: minimum 10 ml/min (measured with MDRD), admitted in our hospital
o Informed Consent
o Man/Women between 18 and 85 years
o Understanding and knowledge of the dutch language

Exclusion criteria

o Instable angina pectoris, heart failure NYHA class IV
o Therapy with erythropoetin, melatonin or/and hypnotics
o Acute renal failure or rapidly progressive glomerulonephritis
o Bleeding or haemolysis as a cause of anaemia
o Deficiency of iron, folate and/or vitamin B12
o Presence of chronic inflammatory disease or clinically significant infection
o Haemoglobinopathies
o Alcohol and/or drug abuse
o Enrolment in another study
o Any kind of disorder that compromises the ability of the subject to give written informed consent and/or to comply with study procedures

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2007
Enrollment:	32
Type:	Actual

Ethics review

Approved WMO

Date:	11-05-2007
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
CCMO	NL16632.100.07