Melatonin rhythm in older ICU patients with and without delirium

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To investigate whether peak melatonin level and daily secretion patterns differ between delirious and non-delirious older persons admitted to the ICU. To determine factors that potentially influence the association between delirium and melatonin...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Deliria (incl confusion)
Study type	Observational invasive

Summary

ID

NL-OMON41099

Source
ToetsingOnline

Brief title
Melatonin rhythm in older ICU patients

Condition

- Deliria (incl confusion)

Synonym
acute confusial state, delirium

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Delirium, Elderly, ICU, Melatonin

Outcome measures

Primary outcome

The primary endpoint will be the differences in the maximal concentration of melatonin in critically ill elderly with or without delirium during ICU admission.

Secondary outcome

Secondary outcomes will be the (differences in) melatonin secretion pattern, defined as the percentage peak melatonin concentration that are secreted between 23pm and 6am, in older persons with and without delirium for seven consecutive days.

Also, we will study if sepsis, mechanical ventilation, renal failure or (nor) adrenergic stimulation influence melatonin secretion patterns in patients admitted to the ICU.

Study description

Background summary

Delirium is a common problem in elderly persons admitted to the ICU. Earlier studies observed an altered secretion pattern and low plasma concentration of melatonin in delirious ICU patients, suggesting that disturbances in the circadian rhythm could be a possible cause for the development of delirium. However, these earlier studies were in small groups and in varying conditions, with contradicting results. The aim of this proposal is to investigate in a larger cohort whether melatonin peak concentrations and secretion patterns differ between delirious and non-delirious elderly patients during ICU admission. Because much is still unknown about the aetiology of delirium, this

would contribute to our body of knowledge.

Study objective

To investigate whether peak melatonin level and daily secretion patterns differ between delirious and non-delirious older persons admitted to the ICU. To determine factors that potentially influence the association between delirium and melatonin levels.

Study design

Case-comparison prospective, multi-centre, observational study.

Study burden and risks

Waste material of daily blood samples taken for clinical reasons will be analysed. If there is no blood sample taken for clinical reasons around 3am, 6am, 3pm and 11pm, a blood sample of 2ml will be collected via an, -already present-, arterial or venous catheter in order to minimize eventual burden. We aim to obtain 4 samples a day, of which we estimate a maximum of 2 samples will have to be collected just for study purposes. Approximately 2 millilitres of blood is needed to measure the melatonin concentration. Blood samples will be collected until ICU discharge or for a maximum of 7 consecutive days. We estimate that we will have to collect maximal 28 ml of blood just for study purposes.The risks in this study are associated with collecting blood samples, and these are considered to be very low.

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

- Age 60 years or above
- Patients or their legal representative must be able to give informed consent
- Inclusion directly after ICU admission, but at least within 24 hours of admission
- Expected admission to the ICU for longer than one day
- Medical or surgical reason for admission to the ICU

Exclusion criteria

- Stroke as the reason for hospital admission
- Chronic use of antidepressants or antipsychotics before ICU admission
- Use of melatonin before or during hospital admission
- Dialysis before admission
- History of diagnosed dementia
- Absence of arterial or central venous catheter

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2014
Enrollment:	142
Type:	Actual

Ethics review

Approved WMO Date:	15-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-05-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL47935.018.14