Melatonin rhythm in older ICU patients

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24047

Source
Nationaal Trial Register

Health condition

Delirium, circadian rhythm, acute confusional state, ICU delirium, delier, acute verwardheid, melatonin, melatonine, circadiane ritme, elderly, ouderen

Sponsors and support

Primary sponsor: Academic Medical Centre Amsterdam
Source(s) of monetary or material Support: Academic Medical Centre Amsterdam

Intervention

Outcome measures

Primary outcome

To study the peak concentration and the secretion patterns of melatonin of older persons admitted to the ICU with and without delirium during the study days at a maximum of seven consecutive days.

Secondary outcome

To investigate whether, besides delirium, mechanical ventilation, renal failure, sepsis or (nor) adrenergic stimulation influence melatonin in patients admitted to the ICU

Study description

Background summary

Rationale: 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 study 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.
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 population: 142 consecutive patients aged 60 years and above admitted to the ICU for a medical or surgical reason.
Main study parameters/endpoints: 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 outcomes will be the (differences in) melatonin secretion pattern 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.
Methods: Patients will be included directly after ICU admission. Informed consent will be obtained from the patient or his/her legal representative. Detailed daily assessments of delirium and sedation will be performed according to ICU routine, respectively with the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) and the Richmond Agitation Sedation Score (RASS). From the medical chart we will collect co-medication, reason for admission, other laboratory measurements taken for clinical reasons, weight, and APACHE II score. 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 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. Blood samples will be collected until ICU discharge or for a maximum of 7 consecutive days. Melatonin will be determined by Radio Immuno Assay (RIA).

Study objective

Disturbances in the circadian rhythm could be a possible cause for development of delirium.

Study design

Discharge from the ICU or 7 days after inclusion.

Intervention

This is an observational study. 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 will be collected via an, -already present-, arterial or venous catheter in order to minimize eventual burden. Blood samples will be collected until ICU discharge or for a maximum of 7 consecutive days.

Contacts

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Eligibility criteria

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 venous catheter

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

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

Ethics review

Positive opinion

Date:	11-02-2014
Application type:	First submission

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
NTR-new	NL4294
NTR-old	NTR4438
CCMO	NL49735.018.14

Study results