Melatonin rhythm in older ICU patients

Gepubliceerd: 11-02-2014 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24047

Bron
NTR

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Centre Amsterdam
Overige ondersteuning: Academic Medical Centre Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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

Onderzoeksopzet

Discharge from the ICU or 7 days after inclusion.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2014
Aantal proefpersonen:	142
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	11-02-2014

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten