Circadian rhythms in critically-ill children – an observational study

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Critical illness, along with the lack of zeitgebers on the PICU environment, and iatrogenic influences like medication and procedures, results in disturbed circadian rhythms in critically ill children, which is important for their recovery.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Exposures, chemical injuries and poisoning
Study type	Observational invasive

Summary

ID

NL-OMON20589

Source
NTR

Brief title
Critical Clock

Condition

- Exposures, chemical injuries and poisoning

Health condition

Critical illness in general

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC - Sophia Children's Hospital
Source(s) of monetary or material Support: Department of Surgery, Division of Pediatric Critical Care

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

To describe the distributions of rhythmic parameters in the paediatric ICU and their evolution during PICU stay.

Secondary outcome

1. To identify the correlations between different circadian rhythm parameters. 2. To construct a robust combined measure of circadian rhythmicity from these parameters. 3. To assess the accuracy of combinations of vital signs in determining underlying circadian rhythm with the constructed measure mentioned in secondary objective 2 as a reference. 4. To determine the association between circadian rhythms in relation with both patient and disease characteristics on one hand and outcome on the other.

Study description

Background summary

Many processes in the human body show variations during every 24 hours, which is called the circadian rhythm. This rhythm is vital for normal homeostasis. In critically-ill adults circadian disturbances have been associated with increased sepsis severity and length of ICU stay, whereas in children little research has been performed. The intensive care unit necessitates a multi-faceted approach in the study of circadian rhythms, although this approach has not been used yet. This study will assess the status of the circadian rhythm of critically-ill children in biomarkers, vital signs, sleep, and gene expression, along with its role in critical illness.

Study objective

Critical illness, along with the lack of zeitgebers on the PICU environment, and iatrogenic influences like medication and procedures, results in disturbed circadian rhythms in critically ill children, which is important for their recovery.

Study design

PICU admission

Intervention

None

Contacts

Public
Erasmus MC
Arnout Cramer

Not available
Scientific
Erasmus MC
Arnout Cramer

Not available

Eligibility criteria

Age
Newborns
Newborns
Babies and toddlers (28 days-23 months)
Babies and toddlers (28 days-23 months)
Children (2-11 years)
Children (2-11 years)
Adolescents (12-15 years)
Adolescents (12-15 years)
Adolescents (16-17 years)
Adolescents (16-17 years)

Inclusion criteria

- All children with an expected PICU-stay of at least two days.

Exclusion criteria

- Preterm, i.e. postconceptional age of <37 weeks, on admission - Syndrome associated with

severe mental retardation, except for trisomy 21 - Hydrocortison use in the 3 days prior to admission - Melatonin use within 24 hours prior to admission - Transfer from another PICU or NICU - Weight < 2.0 kg - Expected not to receive arterial line during study period - Previously included in this Critical Clock study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2022
Enrollment:	25
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Plan description
Not applicable

Ethics review

Approved WMO

Date:	03-11-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

ID: 49654
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL8533
CCMO	NL72597.078.20
OMON	NL-OMON49654

Study results

Summary results
Not applicable