Jet-Lag na Chirurgie

No registrations found.

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

Summary

ID

NL-OMON26425

Source
Nationaal Trial Register

Brief title
CLOCKS (Could jet-Lag be caused by Operations: improving Circadian rhythm Knowledge in Surgery)

Health condition

Disruption of the circadian rhythm, causing short- and long-term health hazards, such as reduced sleep quality and cognitive performance and increased cardiovascular disease risk.

Sponsors and support

Primary sponsor: Amsterdam UMC, locatie AMC
Source(s) of monetary or material Support: Department of Anesthesiology AUMC

Intervention

Outcome measures

Primary outcome

Shift in midpoint sleep as measured by MCTQ-NL

Secondary outcome

Sleep quality as measured by the PSQI-NL, biochemical data on metabolism (such as glucose)

if available (i.e. when collected during admission)

Study description

Background summary

Rationale
Every person has an 'internal clock', regulating daily patterns like sleep-wake behaviour, hormone release, immune system activity and metabolism, consisting of a ‘master clock’ in the hypothalamus (suprachasmatic nucleus) and peripheral clocks elsewhere. In order to keep the clock set to the right external time, stimuli called Zeitgebers (='timegivers' in German) are used, the best known stimulus on the internal clock being daylight. If the SCN and peripheral clocks become misaligned with each other or the external (both the 'solar time' and 'social time), this can cause disruption of sleeping patterns and negative health effects as shown in research studying jet-lag after a long flight, shift workers and daylight savings time. Animal studies have shown several anesthetics to be potential Zeitgebers as well, causing shifts in circadian rhythm and its associated potential health hazards. However, at this moment it is unknown how the human circadian rhythm is affected by anesthesia.

Objective
To study how circadian rhythm is affected by general anesthesia in patients undergoing elective surgery and how these effects are negated by time of administration

Study Design
We will perform a single-centre prospective cohort study.

Study population

Study 1:
To be able to detect a phase shift of 0.3 hours as reported in earlier research, with the reported standard deviation of 0.8 hours, we need a sample size of at least 58 adult patients undergoing elective surgery to obtain the effect-size (Cohen’s d) at a significance level of 0.05 (ß 0.8).

Study 2:
To be able to detect a difference between morning vs. afternoon surgery, we need a sample size of at least 260 adult patients undergoing elective surgery. 130 patients where surgery starts in the morning (08:00-13:00) and 130 patients where surgery starts in the afternoon (13:00-18:00).

Main study outcome
The main outcome parameter is a disruption or shift in circadian rhythm quantified by questionnaires, comparing chronotype and sleep quality before and in the 7 days after surgery, and whether this shift is more profound when operated at a specific time of day.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness
There are no risks associated with participation in this study, as all patients will receive standard anesthesia and hospital care, and no additional interventions as a result of this study. Possible benefit is a better understanding of how anesthetics affect circadian rhythm, a step on the way in reducing post-operative disturbance of circadian rhythm and the associated complications.

Study objective

General anesthesia disturbs circadian rhythm in patients undergoing surgery, with effects being influenced by a person's chronotype and the time of the procedure relative to the patients internal clock

Study design

Inclusion
Patients coming into the outpatient anesthesiology pre-assessment clinic will be asked if they object to being called by phone for more information on the study. If they do not object, they will be called 3 days before surgery receiving information about the study and asked to participate.

Data collection
Participants will fill out the Munich-ChronoType Questionnaire (MCTQ) and Pittsburgh Sleep Quality Index (PSQI) to determine chronotype and sleep quality before surgery on the day of inclusion. In the following 10 nights (3 before surgery, 7 after), a modified version of the MCTQ is used as a sleep log. On the 7th day post-surgery, the sleep log is handed in, and patients are asked to fill out the PSQI again reporting sleep quality since surgery. Data on peri-operative drug use (e.g. glucocorticoids) and hospital admission are de-identified and extracted from the electronic patient records as well.

Contacts

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Eligibility criteria

Inclusion criteria

- Adult patients
- Scheduled for elective surgery
- Use of any form of general anesthesia (e.g. propofol, flurane-gas)

Exclusion criteria

- ASA score of 3 or higher
- Cardiac surgery
- Scheduled for post-operative admission on ICU-ward
- Post-operative delirium

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	14-06-2020
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	11-06-2020
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	NL8709
Other	METC AMC : W20_263

Study results