

Jet-Lag na Chirurgie

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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 patient's internal clock

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

Samenvatting

ID

NL-OMON26425

Bron

Nationaal Trial Register

Verkorte titel

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

Aandoening

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.

Ondersteuning

Primaire sponsor: Amsterdam UMC, locatie AMC

Overige ondersteuning: Department of Anesthesiology AUMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Shift in midpoint sleep as measured by MCTQ-NL

Toelichting onderzoek

Achtergrond van het onderzoek

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 (suprachiasmatic 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 (β 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.

Doel van het onderzoek

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 patient's internal clock

Onderzoeksopzet

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	14-06-2020
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum: 11-06-2020

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	NL8709
Ander register	METC AMC : W20_263

Resultaten