Efficacy of Sodium Oxybate to promote sleep in the ICU: A randomized controlled trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25983

Source
Nationaal Trial Register

Brief title
SENSEI

Health condition

Sleep disruption in the ICU

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Jazz Pharmaceuticals

Intervention

Outcome measures

Primary outcome

Sleep efficiency during the designated ICU night period between 22:00 hrs and 06:00 hrs, as determined by polysomnography (PSG) on the second study night.

Secondary outcome

- total sleep time, sleep fragmentation index and total amount of slow wave sleep as determined by polysomnography on the second study night;
- total sleep time per night assessed by actigraphy;
- incidence of delirium;
- outcome parameters of patient- and nurse-derived sleep questionnaire scores (RCSQ).

Study description

Background summary

We aim to include 50 patients who are experiencing sleep disruption and will randomize these between two treatment arms: standard treatment (temazepam) versus SXB during three consecutive nights. Sleep scores will be obtained as well as polysomnography on the second study night in both groups. To study the quality of sleep in our ICU we already implemented subjective nurse driven sleep scoring. This facilitates recognition and quantification of the current problems regarding sleep in our patient.

Study objective

Sodium oxybate is better at improving sleep efficiency in ICU patients with sleep disruption than temazepam.

Study design

3 nights of study drug administration

Intervention

In this pilot study, a double-blind double-dummy design will be used. One group will receive standard care i.e. temazepam 1 x 20 mg at 22:00 hr and a placebo preparation of SXB at 22.00 hr and 02.00 hr. The other group will receive SXB 3.5 grams at 22.00 hr, and 3.5 gram at 02.00 hr (or 2 times 2,0 grams in case of a decreased liver function: spontaneously prolonged coagulation time or three times increased transaminase levels above the upper limit of normal), and a placebo preparation of temazepam at 22.00 hr. Upon study drug administration at 22.00 hr patients are asked to attempt to sleep.

Contacts

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Eligibility criteria

Inclusion criteria

Admission to the ICU/MCU;
Expected duration of ICU/MCU admission > 2 nights after detection of sleep difficulties;
Awake, conscious (patients can be intubated);
RASS (Richmond Agitation-Sedation Scale) score ≥ -2;
The patient is experiencing sleep difficulties based on their own or clinical judgment as well as on a low score (<60% average score) on the Richard Campbell Sleep Questionnaire;
The ICU physician intends to prescribe general sleep promoting measures as well as a benzodiazepine because of the sleep problems.

Exclusion criteria

Use of sedatives for sleep problems (for example benzodiazepine use) in the last 3 days, except a low dose of Sufentanil (up to 2,5 µg/hr) in intubated patients since this dose is frequently needed to counteract laryngeal tube irritation;
Current use of haloperidol, except a maintenance dose in patients recovering from a delirium;
RASS score < -2;
Active delirium, as assessed by a ICDSC-NL score > 3;
SSADH-deficiency;
Severe depression;
Planned ICU admission time < 3 nights after detection of sleep difficulties.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	04-06-2019
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	28-08-2019
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	NL7983
Other	METC LUMC : P17.221

Study results