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

Gepubliceerd: 28-08-2019 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25983

Bron
Nationaal Trial Register

Verkorte titel
SENSEI

Aandoening

Sleep disruption in the ICU

Ondersteuning

Primaire sponsor: Leiden University Medical Center
Overige ondersteuning: Jazz Pharmaceuticals

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

3 nights of study drug administration

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	04-06-2019
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	28-08-2019
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	NL7983
Ander register	METC LUMC : P17.221

Resultaten