

Effect of propofol on sleep quality of critically ill patients

Submission date 15/10/2009	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 29/10/2009	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 29/10/2009	Condition category Other	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Effect of propofol on sleep quality of critically ill patients: a randomised placebo controlled cross-over trial

Acronym
Propofol vs Placebo

Study objectives

To assess the effect of propofol on sleep quality of mechanically ventilated critically ill patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of University Hospital of Heraklion, Crete approved on the ... (ref: 11868)

Primary study design

Interventional

Study design

Randomised placebo-controlled cross-over trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Critically ill patients

Interventions

Each patient will be studied on two consecutive nights (from 9:00 pm to 7:00 am). In each patient two nights polysomnography studies will be performed with or without propofol in random order. Propofol will be administered via continuous infusion. The rate (mc/Kgr/min) of sedation will be such as to achieve a score of 3 on the Ramsay Scale (response to commands) with no changes in the infusion rate during the study time. Single doses of sedatives or changes in the rate of infusion of sedatives will be not permitted during the study or for 4 hours before the study. Patients in whom the requirements for sedation as judged by the primary physician increased during the night will be excluded for further study and the study will be terminated at that point. The Ramsay Scale will be re-evaluated at the beginning (9:00pm) at the middle (2:00pm) and end (7:00am) of the study.

Patients will be followed up until their discharge from the hospital.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Propofol

Primary outcome(s)

1. Effect of propofol on sleep quality, measured immediately after each study night
2. Sleep architecture, scored manually by an expert physician not involved in the study.
3. Central apnoeas, arousals and awakenings, defined using standard criteria
4. Total sleep fragmentation, calculated as the sum of arousals and awakenings per hour of sleep

Key secondary outcome(s)

Not provided at time of registration

Completion date

05/10/2010

Eligibility

Key inclusion criteria

1. Critically ill patients, on mechanical ventilation for at least 48 hours, haemodynamically stable
2. Ventilated on assist mode
3. No respiratory distress
4. Aged between 18 and 85 years, inclusive, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Other

Sex

All

Key exclusion criteria

1. Aged less than 18 and greater than 85 years
2. Severe haemodynamic instability
3. Pregnancy
4. End stage disease
5. Respiratory distress
6. Acute brain injury

Date of first enrolment

20/10/2009

Date of final enrolment

05/10/2010

Locations

Countries of recruitment

Greece

Study participating centre

Intensive Care Unit

Crete
Greece
71110

Sponsor information

Organisation

Cretan Critical Care Society (Greece)

Funder(s)

Funder type

Research organisation

Funder Name

Cretan Critical Care Society (Greece)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration