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Effect of propofol on sleep quality of critically ill patients

Submission date
15/10/2009

Recruitment status
No longer recruiting

Registration date
29/10/2009

Overall study status
Completed

Last Edited
29/10/2009

Condition category
Other

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] 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

Protocol serial number
N/A

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)

Study design
Randomised placebo-controlled cross-over trial

Primary study design
Interventional

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes