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Effect of propofol on sleep quality of critically ill patients

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
20/10/2009

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

Age group
Other

Sex
Both

Target number of participants
10

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)

Sponsor details
Intensive Care Unit
University Hospital of Heraklion
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Sponsor type
Research organisation

Website
http://www.icuheraklion.gr

Funder(s)

Funder type
Research organisation

Funder Name
Cretan Critical Care Society (Greece)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration