

# Effect of propofol on sleep quality of critically ill patients

<b>Submission date</b> 15/10/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 29/10/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 29/10/2009	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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