

Randomised trial of daily interruption of sedative infusions in adult medical-surgical intensive care unit

Submission date 17/11/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 23/04/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/08/2021	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Randomised trial of daily interruption of sedative infusions in adult medical-surgical intensive care unit

Study objectives

To access the efficacy of daily interruption of sedative infusions versus interruption guided by the physician.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Ethics Board of University Hospital of Heraklion, Crete, on the 23rd November 2004 (ref: 10860).

Study design

Randomised trial

Primary study design

Observational

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Sedation in critically ill patients

Interventions

Daily interruption of sedative infusions. If during this process the patient needs sedation again then the sedation restarts at half the previous dose and adjusted to reach the desired level of sedation.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. Duration of stay in intensive care
2. Duration of mechanical ventilation
3. Length of stay in the hospital

Secondary outcome measures

1. Mortality in the intensive care
2. Mortality in the hospital
3. Doses of sedatives
4. Number of diagnostic tests of the brain

Overall study start date

25/11/2004

Completion date

20/03/2006

Eligibility**Key inclusion criteria**

Critically ill patients receiving sedation for 48 hours.

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

100

Total final enrolment

97

Key exclusion criteria

1. Pregnancy
2. Patients first-sedated in another hospital
3. Patients after CardioPulmonary Resuscitation (CPR)

Date of first enrolment

25/11/2004

Date of final enrolment

20/03/2006

Locations

Countries of recruitment

Greece

Study participating centre

Intensive Care Unit

Heraklion

Greece

71110

Sponsor information

Organisation

Cretan Critical Care Society (Greece)

Sponsor details

Intensive Care Unit

Heraklion University Hospital

Voutes

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71110

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Sponsor type

Research organisation

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2009	06/08/2021	Yes	No