ISRCTN69413086 https://doi.org/10.1186/ISRCTN69413086

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

Submission date	Recruitment status	[_] Prospectively registered
17/11/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/04/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/08/2021	Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Stella Anifantaki

Contact details
Intensive Care Unit
Heraklion University Hospital
Voutes
Heraklion
Greece
71110
-
stellaanifa@pathfinder.gr

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
Heraklion
Greece
71110
-
georgop@med.uoc.gr

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