

Daily sedative interruption in critically ill patients being managed with a sedation protocol

Submission date 23/06/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 23/06/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 28/02/2019	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

NCT00675363

Protocol serial number

MCT-85487; 07-0281-A; 08-0135-E

Study information

Scientific Title

SLEAP: a randomised trial of daily sedative interruption in critically ill, mechanically ventilated patients being managed with a sedation protocol

Acronym

SLEAP

Study objectives

To determine whether critically ill, mechanically ventilated adults managed with protocol-directed sedation and daily sedation interruption spend less time on the ventilator and in the intensive care unit (ICU) than patients managed with protocol-directed sedation alone.

The results of the pilot study to this trial can be found at: <http://www.ncbi.nlm.nih.gov/pubmed/18552687>

SLEAP-SCP Trial:

As of 25/02/2010 this record was updated to include details of an add-on trial entitled: 'SLEAP - Sleep, Cognition and Psychology (SLEAP-SCP): psychological, cognitive, and sleep morbidity associated with the use of a sedation protocol versus a sedation protocol and daily sedative interruption in critically ill, mechanically ventilated adults'. All details of this add-on trial can be found in the relevant fields with the subtitle 'SLEAP-SCP Trial'.

This proposed study will add psychosocial outcome measures to the existing SLEAP study in an attempt to determine if patients in either group have a superior psychological outcome.

The anticipated start and end dates of the SLEAP-SCP Trial are as follows:

Anticipated start date: 01/10/2009

Anticipated end date: 01/12/2011

The SLEAP-SCP Trial has a target number of participants of 94, and is recruiting in Canada, as well as the United States of America.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Board of Mount Sinai Hospital (Toronto) approved on the 29th November 2007 (ref: 07-0281-A)

SLEAP-SCP Trial:

Research Ethics Board of Mount Sinai Hospital (Toronto) approved on the 8th July 2008 (ref: 08-0135-E)

Study design

Concealed unblinded randomised multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Mechanical ventilation

Interventions

Experimental group:

Protocol-directed sedation and daily sedation interruption while patient is mechanically ventilated and receiving intravenous sedation infusions.

Control group:

Protocol-directed sedation while patient is mechanically ventilated and receiving intravenous sedation infusions.

Both groups will have sedation and analgesia managed according to their assigned strategy for the duration of their infusions of sedation and/or analgesia in the ICU. At 60 days, all study interventions (e.g., charting of sedation-agitation scale [SAS] and daily data collection) will cease, but patients will be followed for outcomes (e.g., duration of mechanical ventilation [MV], lengths of stay).

SLEAP takes place primarily in the ICU setting. All study interventions and data collection (e.g., charting of SAS or Richmond Agitation Sedation Scale [RASS], and daily data) (Daily Data Forms 4 to 7) will continue while patients are mechanically ventilated and receiving infusions of sedatives /analgesics. If patients remain ventilated and receiving infusions at 60 days, study interventions will cease, but patients will be followed to document clinical outcomes (e.g., duration of MV, ICU and hospital length of stay). Research Coordinators will not record daily data after discontinuation of drug infusions, but will interview patients on days 3 and 28, and 3 months after ICU discharge, to determine recall of ICU events.

SLEAP-SCP Trial:

Patients enrolled in SLEAP will be approached after ICU discharge for consent for SLEAP-SCP. At 1 week and 6 months post-ICU discharge, patients will undergo measurements of psychological variables, using validated instruments for the assessment of post-traumatic stress disorder (PTSD) symptomatology, delirium, neurocognitive impairment, anxiety, depression, sleep impairment, functional recovery following critical illness.

Sponsor details for the SLEAP-SCP Trial:

Canadian Intensive Care Foundation (Canada)

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Canada

T: +1 403 262 2177

F: +1 403 261 6818

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Website: <http://www.cicf.ca/English/Home/english%20home.html>

Contact details for the SLEAP-SCP Trial:

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Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Time to successful extubation measured from intubation to extubation or tracheostomy mask for 48 hours.

SLEAP-SCP Trial:

Extent of depressive, anxiety (Hospital Anxiety And Depression Scale [HADS] scores) and PTSD symptoms (Impact of Events Scale [IES] scores), compared across the two arms of the SLEAP study.

Key secondary outcome(s)

1. ICU and hospital mortality, patients will be followed until hospital discharge or death
2. ICU and length of hospital stay, patients will be followed until hospital discharge or death
3. Adverse events (e.g., self-removal of endotracheal tube), measured while in ICU, receiving sedative/analgesic infusions, and being managed with the SLEAP sedation strategy
4. Delirium, as assessed by the Intensive Care Delirium Screening Checklist, measured while in ICU, receiving sedative/analgesic infusions, and being managed with the SLEAP sedation strategy
5. Reintubation and tracheostomy rates, measured while in ICU, receiving sedative/analgesic infusions, and being managed with the SLEAP sedation strategy
6. Neurologic function, measured while in ICU, receiving sedative/analgesic infusions, and being managed with the SLEAP sedation strategy
7. Patient recall of ICU events, measured on days 1 - 3, 1 month and 3 months post ICU discharge

Completion date

01/06/2010

Eligibility

Key inclusion criteria

1. Aged greater than or equal to 18 years
2. Mechanically ventilated, with anticipated need for mechanical ventilation greater than or equal to 48 hours
3. ICU team has decided to initiate continuous sedative/analgesic infusion(s)
4. Informed consent

Additional SLEAP-SCP Trial inclusion criteria:

1. In an ICU at participating hospitals
2. Aged greater than or equal to 18 years old

3. Intubated and mechanically ventilated
4. Receiving infusions of sedation and/or analgesia
5. Able to speak and understand English

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Admission after resuscitation from cardiac arrest
2. Traumatic brain injury
3. Currently receiving neuromuscular blocking agents (but these patients may be enrolled after these agents are discontinued)
4. Allergy to midazolam and lorazepam
5. Lack of commitment to aggressive treatment
6. Current enrolment in a related trial
7. Previous enrolment in this trial

Additional SLEAP-SCP Trial exclusion criteria:

1. Patients unable to communicate
2. Incompetent to decide on participation

Date of first enrolment

01/01/2008

Date of final enrolment

01/06/2010

Locations**Countries of recruitment**

Canada

United States of America

Study participating centre

Mount Sinai Hospital

Toronto, Ontario

Canada
M5G 1X5

Sponsor information

Organisation

Mount Sinai Hospital (Canada)

ROR

<https://ror.org/05deks119>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-85487)

Alternative Name(s)

Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Funder Name

Canadian Intensive Care Foundation

Alternative Name(s)

CICF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/11/2012	28/02/2019	Yes	No
Results article	results	01/10/2015	28/02/2019	Yes	No
Results article	results	01/08/2016	28/02/2019	Yes	No
Results article	results	01/04/2015	28/02/2019	Yes	No
Results article	results	01/02/2016	28/02/2019	Yes	No