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

Submission date 23/06/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/06/2008	**Overall study status** Completed	
Last Edited 28/02/2019	**Condition category** Surgery	

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
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E: info@cicf.ca
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, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, 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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes