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Inhalative long-term sedation with sevoflurane /remifentanil using the AnaConDa® system

Submission date 28/06/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 31/07/2008	**Overall study status** Completed	
Last Edited 19/05/2022	**Condition category** Signs and Symptoms	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jens Soukup

Contact details
University Hospital Halle (Saale)
Department of Anaesthesiology and Critical Care
Ernst-Grube-Str. 40
Halle
Germany
06120
-
jens.soukup@medizin.uni-halle.de

Additional identifiers

EudraCT/CTIS number
2007-006087-30

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
KKSH-044

Study information

Scientific Title
Efficiency and safety of inhalative long-term sedation with sevoflurane/remifentanil compared to intravenous sedation with propofol/remifentanil in intensive care patients: a prospective randomised clinical trial

Acronym
Anaconda trial

Study objectives
Sedation with inhalative sedation using sevoflurane/remifentanil is more effective compared to intravenous sedation using propofol/remifentanil.

Please note that as of 06/02/09 this record was updated to include information on the ethics approval and the anticipated start date. The initial anticipated start date was 01/09/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 06/02/2009: Ethics Board of the University Halle/Saale (Germany) gave approval in November 2008.

Study design
Prospective randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information

Health condition(s) or problem(s) studied
Sedation

Interventions
Sedation using the AnaConDa® system.

The study protocol implies a randomised prospective study with two groups including 50 patients in each group. Group S will be sedated with sevoflurane and remifentanil and Group P with propofol (disoprivan 2%) and remifentanil for day one to four. From the fifth day only the intravenous propofol is going to be switched to midazolam to avoid the danger of a propfol infusion syndrome. A rescue medication like esketamin or clonidin are allowed when indicated for example for shivering or insufficient sedation depth. There is also the possibility to exchange the remifentanil to sufentanil in both groups if the clinical situation demands it for example because of a persistent bradycardia during the analgosedation.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sevoflurane, remifentanil, propofol

Primary outcome measure
Weaning time (time end of sedation until spontaneous breathing)

Secondary outcome measures
1. Sedation quality (daily assessment, Richmond Agitation Sedation scale, relation between aspired to real sedation depth, frequency of additional boli)
2. Flouride (daily measurement up to 3 days after stop sedation)
3. Cardiac markers (daily measurement up to 3 days after stop sedation)
4. Sedation depth (daily assessment, Richmond Agitation Aedation scale, BIS-Monitoring)

Overall study start date
08/01/2009

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Aged older than 18 years, either sex
2. Critically ill patients with mechanical ventilation
3. Need analgosedation for more than 48 hours

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Pregnancy
2. Primary unfavourable prognosis

Date of first enrolment
08/01/2009

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital Halle (Saale)
Halle
Germany
06120

Sponsor information

Organisation
University Hospital Halle (Saale) (Germany)

Sponsor details
Department of Anaesthesiology and Critical Care
Ernst-Grube-Str. 40
Halle
Germany
06120
-
jens.soukup@medizin.uni-halle.de

Sponsor type
Hospital/treatment centre

Website

http://www.medizin.uni-halle.de/

ROR
https://ror.org/04fe46645

Funder(s)

Funder type
Industry

Funder Name
Investigator initiated study, in parts funded by:

Funder Name
Sedana Medical (Sweden)

Funder Name
Draeger Medical Inc. (USA)

Funder Name
University Hospital Halle (Saale) (Germany)

Funder Name
Abbott Deutschland (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/08/2012		Yes	No
Basic results		16/05/2021	19/05/2022	No	No