

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

Submission date 28/06/2008	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 31/07/2008	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 19/05/2022	Condition category Signs and Symptoms	☐ 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)
2007-006087-30

Protocol serial number
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.

Primary study design

Interventional

Study design

Prospective randomised clinical trial

Study type(s)

Treatment

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 propofol 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, remifentanyl, propofol

Primary outcome(s)

Weaning time (time end of sedation until spontaneous breathing)

Key secondary outcome(s)

1. Sedation quality (daily assessment, Richmond Agitation Sedation scale, relation between aspired to real sedation depth, frequency of additional boli)
2. Fluoride (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 Sedation scale, BIS-Monitoring)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

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