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A randomised, double-blinded, multicentre, parallel group study comparing a remifentanil-regimen with a fentanyl-regimen for analgesia in mechanically ventilated patients

Submission date
09/07/2007

Recruitment status
No longer recruiting

Registration date
03/10/2007

Overall study status
Completed

Last Edited
19/05/2022

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Claudia Spies

Contact details
Chariteplatz 1
Berlin
Germany
10117
+49 (0)30 450 531 012/52
claudia.spies@charite.de

Additional identifiers

EudraCT/CTIS number
2005-001907-21

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
911

Study information

Scientific Title
A randomised, double-blinded, multicentre, parallel group study comparing a remifentanil-regimen with a fentanyl-regimen for analgesia in mechanically ventilated patients

Acronym
ZORA

Study objectives
There is a difference in analgetic quality and controllability between remifentanil and fentanyl.

Please note that, as of 08/01/09, the anticipated end date of this trial has been updated from 01 /12/2008 to 30/06/2009.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The local ethics committee (Ethics board committee Berlin, Landesamt fur Gesundheit und Soziales [LaGeSo], Berlin) was informed throughout and gave permission for the performance of this clinical trial on the 25th October 2007 (ref: EA 1/125/05).

Study design
Randomised controlled double-blind parallel-group multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Analgesia in mechanical ventilation

Interventions
In this study the effectiveness and quality of two different analgesia regimes in mechanically ventilated patients is compared:
1. Remifentanil (5 mg/50 ml) 0.1 - 0.4 µg/kg/min

2. Fentanyl (1 mg/50 ml) 0.02 - 0.08 µg/kg/min
Duration of the treatment: minimum 24 hours, maximum 30 days
Frequency: continuous intravenous (iv) application
Follow up: on discharge from ICU, after 30 days and from discharge 6 and 12 months

Additional sedation with propofol or midazolam allowed:
Propofol (1000 mg/50 mg) 0.8 - 4 mg/kg/h
Midazolam (90 mg/50 ml) 0.01 - 0.18 mg/kg/h
Frequency: continuous iv application

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Remifentanil, fentanyl

Primary outcome measure
According to the different analgetic treatment the target values of sedation and analgesia must be reached. The following endpoints will be measured every hour for the first 6 hours after the start of the study drug, then every 4 hours for the first 24 hours after the start of the study drug. Thereafter every 8 hours until the end of the study (maximum 30 days):
1. Richmond Agitation Sedation Scale (RASS)
2. Behavioural Pain Scale (BPS)
3. Visual Analogue Scale (VAS)
4. Delirium Detection Scale (DDS)

Secondary outcome measures
1. On admission: Acute Physiology And Chronic Health Evaluation II (APACHE II) score
2. Continuous:
2.1. Electrocardiogram (ECG)
2.2. Blood pressure
2.3. Heart rate
3. Every 8 hours:
3.1. Patient examination
3.2. Temperature
3.3. Volume balance
4. Daily:
4.1. Laboratory (including Prothrombin Consumption Time [PCT], Red Blood Cell count [RBC], White Blood Cell count [WBC], electrolytes, International Normalised Ratio [INR], Partial Thromboplastin Time [PTT], creatinine, urea, bilirubin)
4.2. ICU Scores (Simplified Acute Physiology Score II [SAPS II], Sequential Organ Failure Assessment [SOFA] score, 28-item Therapeutic Intervention Scoring System [TISS 28] score)
4.3. Ventilation parameter
4.4. Weaning protocol
4.5. Adverse events
4.6. Serious adverse events
4.7. Nosocomial infections
4.8. Duration of mechanical ventilation

4.9. Total dosage of analgetics
4.10. Total dosage of sedatives
5. On discharge from ICU, and 6 and 12 months after discharge:
5.1. Quality of life
5.2. Post Traumatic Stress Disorder (PTSD)

Overall study start date
01/11/2005

Completion date
30/06/2009

Eligibility

Key inclusion criteria
1. Need for Intensive Care Unit (ICU) treatment because of at least one severe illness
2. Expected mechanical ventilation duration greater than 24 hours
3. Present mechanical ventilation duration less than 48 hours
4. Aged greater than 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
160

Key exclusion criteria
1. Expected ICU therapy less than 24 hours
2. Present mechanical ventilation duration greater than 48 hours
3. Expected ventilation duration greater than 24 hours
4. Pregnancy
5. Expected limited cerebral or neurological ability caused by:
5.1. Hypoxic brain damage
5.2. Severe traumatic brain injury
5.3. Cranial mass bleeding
5.4. Dementia
5.5. Parkinson's disease
5.6. Motor Neuron Disease
6. Myasthenia gravis
7. Need for chronical artificial ventilation
8. Chronic-pain patients (World Health Organization [WHO] grade III)

9. Patients with spinal anaesthesia
10. Peridural anaesthesia with opioids
11. Patients with severe illnesses (American Society of Anaesthesiologists [ASA] grade V)
12. Patients who took part on other studies the last 30 days
13. No permission for study treatment

Date of first enrolment
01/11/2005

Date of final enrolment
30/06/2009

Locations

Countries of recruitment
Germany

Study participating centre
Chariteplatz 1
Berlin
Germany
10117

Sponsor information

Organisation
Charite - University Medicine Berlin (Charite - Universitatsmedizin Berlin) (Germany)

Sponsor details
Universitatsklinik fur Anasthesiologie und operative Intensivmedizin
Klinikdirektorin: Prof. C. Spies
Augustenburger Platz 1
Berlin
Germany
13353

Sponsor type
Hospital/treatment centre

Website
http://www.charite.de/ch/anaest/

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline Beecham (UK)

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?
Basic results		03/09/2020	19/05/2022	No	No