

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

Submission date 09/07/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 03/10/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 19/05/2022	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

2005-001907-21

Protocol serial number

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 für 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

Study type(s)

Treatment

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(s)

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)

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 chronic 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 - Universitätsmedizin Berlin) (Germany)

ROR

<https://ror.org/001w7jn25>

Funder(s)

Funder type

Industry

Funder Name

GlaxoSmithKline Beecham (UK)

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