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# Prospective, randomised, double-blinded clinical trial on remifentanil for analgesia and sedation of ventilated neonates and infants

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 15/11/2006 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 03/01/2007 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 10/04/2019 | Signs and Symptoms | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**
NCT00419601

**Secondary identifying numbers**
KKSK-251

# Study information

### Scientific Title
Prospective, randomised, double-blinded clinical trial on remifentanil for analgesia and sedation of ventilated neonates and infants

### Acronym
RAPIP

### Study objectives
It shall be investigated whether ventilated neonates and infants with a remifentanil based analgesia and sedation can be extubated faster after discontinuation of the opioid infusion compared to neonates and infants with a fentanyl based analgesia and sedation.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics approval received from the Ethics Committee of the Medical Faculty of the University of Cologne on the 18 August 2006 (ref. no.: 06-053).

### Study design
Randomised, controlled, double-blind, two-armed parallel group 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/sedation

### Interventions
Test group:
Permanent remifentanil infusion with a primary dose of 9 microgram/kg/h titrated to the individual need of the test person up to a maximum dose of 30 microgram/kg/h.

Comparison group:
Permanent fentanyl infusion with a primary dose of 3 microgram/kg/h titrated to the individual need of the test person up to a maximum dose of 10 microgram/kg/h.

The maximum duration of infusion of the test substance is 96 hours. Sedation may be continued if necessary using fentanyl.

Please note that as of 04/05/10 this record has been updated. The duration of this trial extended from 17/08/08 and was completed on 11/04/10. The original target number of participants was 20.

### Intervention Type
Drug

### Phase
Not Specified

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

### Primary outcome measure
Shortening of the artificial ventilation after discontinuation of the opioid infusion.

### Secondary outcome measures
1. Documentation of the efficacy and safety of a remifentanil based analgesia and sedation of ventilated newborns and infants
2. Documentation of a potentially occuring tolerance to the analgesic effect of the opioids
3. Documentation of a potentially occuring hyperalgesia after discontinuation of the opioid infusion
4. Documentation of possible withdrawal symptoms on both treatment groups after extubation
5. Documentation of the discharge time from the Paediatric Intensive Care Unit (PICU) after discontinuation of the opioid infusion

### Overall study start date
17/11/2006

### Completion date
17/08/2008

## Eligibility

### Key inclusion criteria
1. Ventilated term newborns and infants less than 60 days
2. Expected time of artificial ventilation between 12 and 96 hours

### Participant type(s)
Patient

### Age group
Neonate

### Sex
Not Specified

### Target number of participants
24

### Key exclusion criteria
1. Neuromuscular diseases
2. Drug abuse of the mother (exclusion criteria for newborns)
3. Known hypersensitivity to Ultiva® and Fentanyl-Janssen®
4. Missing informed consent of the parents
5. Participation in another clinical trial during the last four weeks before start of this trial

### Date of first enrolment
17/11/2006

### Date of final enrolment
17/08/2008

## Locations

### Countries of recruitment
Germany

### Study participating centre
### Clinic for Paediatrics
Cologne
Germany
50937

## Sponsor information

### Organisation
University of Cologne (Germany)

### Sponsor details
c/o Professor Dr. Bernhard Roth
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### Sponsor type
University/education

### Website
http://www.uni-koeln.de

**ROR**
https://ror.org/00rcxh774

# Funder(s)

**Funder type**
Industry

**Funder Name**
GlaxoSmithKline GmbH & Co. KG, Munich (Germany) - partially funded

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/06/2012 | 10/04/2019 | Yes | No |