

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

Submission date 15/11/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/01/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/04/2019	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
Prof Bernhard Roth

Contact details
Clinic for Paediatrics
University of Cologne
Kerpener Str. 62
Cologne
Germany
50937

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00419601

Protocol serial number
KKSK-251

Study information

Scientific Title

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

Acronym

RAPIP

Study objectives

It shall be investigated whether ventilated neonates and infants with a remifentanyl 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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Analgesia/sedation

Interventions

Test group:

Permanent remifentanyl 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(s)

Shortening of the artificial ventilation after discontinuation of the opioid infusion.

Key secondary outcome(s)

1. Documentation of the efficacy and safety of a remifentanil based analgesia and sedation of ventilated newborns and infants
2. Documentation of a potentially occurring tolerance to the analgesic effect of the opioids
3. Documentation of a potentially occurring 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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

Not Specified

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)

ROR

<https://ror.org/00rcxh774>

Funder(s)

Funder type

Industry

Funder Name

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

Results and Publications

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				

[Results article](#)

01/06/2012

10/04/2019

Yes

No