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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

ClinicalTrials.gov (NCT)
NCT00419601

Protocol serial number
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).

Primary study design
Interventional

Study design
Randomised, controlled, double-blind, two-armed parallel group trial.

Study type(s)
Treatment

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(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 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

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