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Prospective, multicentre, randomised, double-blinded and placebo-controlled clinical trial on the efficacy and safety of clonidine as a co-medication in analgesia and sedation of long-term-ventilated neonates and infants

Submission date 10/07/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 20/01/2004	**Overall study status** Completed	
Last Edited 07/04/2015	**Condition category** Neonatal Diseases	

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

Secondary identifying numbers

N/A

Study information

Scientific Title
Prospective, multicentre, randomised, double-blinded and placebo-controlled clinical trial on the efficacy and safety of clonidine as a co-medication in analgesia and sedation of long-term-ventilated neonates and infants

Study objectives
PAED-Net (P-N) is a corporation of clinical trial coordination centers (KKS) with specific paediatric sections at 6 German universities. The coordinating center of P-N is located at the KKS in Mainz (Prof. Dr. F. Zepp). The intention of P-N is to improve pharmacological trials in childhood according to GCP/ICH. The proposed study is financed by the BMBF with the aim to demonstrate the successful cooperation of the P-N.
Scientific background: A long-term mechanical ventilation of neonates and infants under medical and ethical aspects is only possible with adequate analgesia and sedation usually by opioids, barbiturates and benzodiazepines. The use of these agents can be complicated by adverse events, tolerance and physical dependence. Clonidine (C) is a centrally acting alpha2-agonist with analgesic and hypnotic properties. By a sympatolysis, C suppresses physical withdrawal-symptoms. There is preliminary data showing a possible benefit of C in reducing the dosage of opioids and other centrally-acting agents as well as in reducing the withdrawal-symptoms after cessation of these agents [1]. Preliminary data exists, demonstrating cardiovascular stability in children undergoing heart-surgery and receiving C (1 µg/kg/h) [2].
Aim: Reduction of the consumption of fentanyl, midazolame and thiopentone (mg/kg) beginning with infusion of C or placebo (4th day of ventilation) over 3 days. Reduction of withdrawal-symptoms. Pharmacokinetics of C.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration.

Study design
Multicentre randomised double-blind placebo-controlled 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
Long-term ventilated infants

Interventions
Clonidine (1 µg/kg/h) or placebo is given with the 4th day of ventilation. Analgesics and sedatives are fentanyl, midazolame and thiopentone.
Following cessation of analgesics and sedatives, clonidine is reduced stepwise.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Clonidine, fentanyl, midazolame and thiopentone

Primary outcome measure
A positive confirmation of the hypothesis can lead to an extension of the licensing of C by the manufacturer. Implementation of C in the therapy of long-term ventilated newborns and infants by implementation of the results in the guidelines of the medical societies is desirable. A successful performance of the study is intended to ameliorate the situation of pharmacological trials in childhood in Germany by extension of the infrastructure of the P-N.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
31/07/2003

Completion date
31/12/2006

Eligibility

Key inclusion criteria
Term-newborns, infants ≤24th month of life. Expected duration of ventilation: 6 days.

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
210

Key exclusion criteria
1. Any contraindication to clonidine application:
1.1 Hypotone, catecholamine and volume-refractory circulation problems
1.2 Dysfunction of cardiac excitation, like atrioventricular blocks second and third degree, sick sinus syndrome
1.3 Relevant circulation-effective bradycardias
1.4 Hypersensitivity against clonidine or any other component of the drug
2. Any circumstances, which make the evaluation of pain sensation impossible (for example coma, severe brain injury, hypoxic-ischemic brain injury, neurological or neuromuscular illnesses, application of muscle relaxants (except short-time application for intubation and application at the first day of ventilation)
3. Newborns: anamnestic evidence for drug abuse of the mother (for example psychopharmaca, opioids)

Date of first enrolment
31/07/2003

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Germany

Study participating centre
University Hospital of Cologne
Cologne
Germany
50931

Sponsor information

Organisation
University Hospital of Cologne (Germany)

Sponsor details
Joseph-Stelzmann-Str. 9
Cologne
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05mxhda18

Funder(s)

Funder type
Industry

Funder Name
Federal Ministry of Education and Research (Germany)

Alternative Name(s)
Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Germany

Funder Name
Boehringer Ingelheim (Germany)

Alternative Name(s)
Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, BI, BIPI

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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	01/07/2014		Yes	No