

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

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Registration date 20/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/04/2015	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration.

Completion date

31/12/2006

Eligibility**Key inclusion criteria**

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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)

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 Research, Technology and Space, Bundesministerium für Bildung und Forschung, 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

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