

# 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

<b>Submission date</b> 10/07/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 20/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/04/2015	<b>Condition category</b> 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

## 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  $\leq 24$ 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?
<a href="#">Results article</a>	results	01/07/2014		Yes	No