

# Premedication for preventing pain in infants undergoing nonurgent breathing tube placement

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<b>Registration date</b> 12/10/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 12/10/2022	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Endotracheal intubation is a medical procedure in which a tube is placed into the windpipe through the mouth or nose. It may cause discomfort and pain, as well as harmful physiological reactions. Analgesics have been found to relieve pain caused by endotracheal intubation. The aim of this study is to evaluate the analgesic effect of combined administration before non-emergency endotracheal intubation in infants.

### Who can participate?

Infants in the neonatal intensive care unit at Children's Hospital of Nanjing Medical University who require endotracheal intubation

### What does the study involve?

Infants are randomly assigned to experimental and control groups. The experimental group are injected with 5% glucose 2 ml + atropine 0.02 mg/kg (1 min) and 5% glucose 2 ml and fentanyl 2 ug/kg (5 min) before endotracheal intubation. The control group are injected with 5% glucose 2 ml (1 min) and 5% glucose 2 ml (5 min) before endotracheal intubation. The degree of pain during the examination is recorded.

### What are the possible benefits and risks of participating?

There are no direct benefits or risks involved in taking part in this study.

### Where is the study run from?

Children's Hospital of Nanjing Medical University (China)

### When is the study starting and how long is it expected to run for?

March 2017 to March 2022

### Who is funding the study?

Children's Hospital of Nanjing Medical University (China)

Who is the main contact?  
Dr Keyu Lu, lukeyu19892001@sina.com

## Contact information

### Type(s)

Principal investigator

### Contact name

Dr Keyu Lu

### Contact details

Guangzhou Road 72  
Nanjing  
China  
210009  
+86 (0)8613951703146  
lukeyu19892001@sina.com

## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

Nil known

## Study information

### Scientific Title

Effectiveness of fentanyl and atropine for premedication of the newborn infant before non-emergency endotracheal intubation: a randomized controlled trial

### Acronym

PBNEEI

### Study objectives

Fentanyl and atropine might decrease the pain response during nonurgent endotracheal intubation in neonates

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 25/05/2017, Children's Hospital of Nanjing Medical University Ethics Committee (72 Guangzhou Road, Nanjing, China; +86 (0)83117281; nanjingnicu@163.com), ref: #201703069

## Study design

Multicenter interventional double-blinded randomized controlled trial

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Premedication for nonurgent endotracheal intubation for preventing pain in neonates with respiratory failure

## Interventions

The research team comprised three research neonatologists, a child health care expert, and three assistants with extensive research and clinical experience. Following the acquisition of informed consent from the guardians, the infants were randomly assigned to either the experimental group or the control group using a computer-generated randomization code. Subjects and intubators are blinded.

The experimental group are intravenously injected with 5% glucose 2 ml + atropine 0.02 mg/kg (1 min) and 5% glucose 2 ml + fentanyl 2 ug/kg (5 min) successively before endotracheal intubation. The control group are intravenously injected with 5% glucose 2 ml (1 min) and 5% glucose 2 ml (5 min) successively before endotracheal intubation.

## Intervention Type

Drug

## Phase

Phase IV

## Drug/device/biological/vaccine name(s)

Fentanyl, atropine

## Primary outcome(s)

1. Behavioural responses measured using the N-PASS score at the time of intubation
2. Analgesic efficacy measured using plasma neuron-specific enolase (NSE), cortisol and endorphins concentrations in venous blood samples before and after intubation

## Key secondary outcome(s)

1. Conditions of endotracheal intubation (difficulty of intubation, the opening and closing state of the glottis, and the children's response to intubation) evaluated using the modified Goldberg score at the time of intubation
2. Adverse reactions evaluated using heart rate (HR), oxygen saturation (SaO<sub>2</sub>) and regional cerebral oxygen saturation (rScO<sub>2</sub>) before and after intubation

## Completion date

01/03/2022

## Eligibility

**Key inclusion criteria**

Children with indications for endotracheal intubation, intravenous access or time to open intravenous access, and able to complete intubation within 15-30 minutes

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Total final enrolment**

80

**Key exclusion criteria**

1. Children with emergency intubation
2. Structural abnormalities of the upper respiratory tract (e.g. Pierre-Robin syndrome, glottic stenosis)
3. Upper digestive tract malformation (such as diaphragmatic hernia)
4. A history of difficulty in endotracheal intubation
5. Central respiratory failure caused by asphyxia or brain injury
6. Children intubated twice or more during treatment

**Date of first enrolment**

30/06/2017

**Date of final enrolment**

30/06/2020

**Locations****Countries of recruitment**

China

**Study participating centre**

**Children's Hospital of Nanjing Medical University**

Guangzhou Road 72

Nanjing

China

210009

**Study participating centre**  
**Children's Hospital of Harbin Medical University**  
No. 57, you yi Road  
Dao li District  
Harbin  
China  
150010

## Sponsor information

**Organisation**  
Children's Hospital of Nanjing Medical University

## Funder(s)

**Funder type**  
Research organisation

**Funder Name**  
Project of Futang Children's Science Foundation (FTCSF-2018-04)

**Funder Name**  
Nanjing Special Fund for Health Science and Technology Development (grant no. 201723007)

## Results and Publications

### **Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date.

### **IPD sharing plan summary**

Data sharing statement to be made available at a later date