

Premedication for preventing pain in infants undergoing nonurgent breathing tube placement

Submission date 10/09/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/10/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/10/2022	Condition category 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

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

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 (SaO₂) and regional cerebral oxygen saturation (rScO₂) before and after intubation

Overall study start date

01/03/2017

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

Age group

Neonate

Sex

Both

Target number of participants

80

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

Sponsor details

Department of Newborn Infants

72 Guangzhou Road

Nanjing

China

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+86 (0)1895179507

chengrui350@163.com

Sponsor type

Hospital/treatment centre

Website

<https://www.njch.com.cn>

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

Publication and dissemination plan

Planned publication in the journal BMC Pediatrics.

Intention to publish date

30/06/2023

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