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Premedication for preventing pain in infants undergoing nonurgent breathing tube placement

Submission date
10/09/2022

Recruitment status
No longer recruiting

Registration date
12/10/2022

Overall study status
Completed

Last Edited
12/10/2022

Condition category
Respiratory

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
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_2) and regional cerebral oxygen saturation ($rScO_2$) 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