

Premedication for intubation in neonates: a randomised controlled trial

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
19/10/2004	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
19/10/2004	Completed	<input checked="" type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
25/08/2009	Surgery	

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

Acronym

PIN

Study objectives

Elective endotracheal intubations are still commonly performed without premedication in many institutions. The hypothesis tested in this study was that morphine given prior to elective intubations in neonates would decrease fluctuations in vital signs, shorten the duration of intubation and reduce the number of attempts.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Endotracheal intubation in neonates

Interventions

Morphine 0.2 mg/kg IV compared to placebo 5 minutes before an endotracheal intubation

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

The study aimed to test the hypothesis that morphine 0.2 mg/kg would decrease fluctuations in vital signs, shorten the duration of the procedure and reduce the number of attempts. The primary outcome was the duration of severe hypoxemia, defined as SpO₂ < 85% with a HR < 90 /min. This was felt to be the most undesirable side effect of endotracheal intubation as cerebral blood flow in neonates is highly dependent upon heart rate.

Key secondary outcome(s))

1. Duration of the procedure
2. Duration of hypoxemia (SpO₂ < 85%)
3. Number of attempts
4. Maximum change in blood pressure from baseline
5. Occurrence of bradycardia (HR < 90/min).

Completion date

30/09/2000

Eligibility

Key inclusion criteria

Newborn infants of all gestations admitted to one Neonatal Intensive Care Unit. Infants of all gestations, admitted to McMaster University Medical Center level III NICU and considered likely to need an elective oral or nasotracheal intubation during their hospital stay, were candidates for inclusion in this study. Families were approached for consent as soon as possible after birth when an elective intubation during their hospital stay seemed likely: if their infant(s) was less than 30 weeks gestation, already ventilated (as endotracheal tubes are frequently changed after 10 days if clinical deterioration from a respiratory standpoint), was on NCPAP for respiratory distress or was needing an elective surgery. Others were approached when an elective intubation was needed. At the time of this study, our unit was a 33-bed level 3 NICU, caring for both inborn and outborn patients, and the referral center for 25000 annual deliveries, with 900-1000 admissions per year.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

1. Absence of an intravenous access
2. Upper airway anomaly potentially leading to a difficult intubation
3. Cyanotic heart disease
4. Upper gastrointestinal obstruction (which would require a rapid sequence intubation)
5. Concurrent opioid administration.

Date of first enrolment

01/12/1999

Date of final enrolment

30/09/2000

Locations

Countries of recruitment

Canada

Study participating centre

CHEO, Dept of Pediatrics

Ottawa

Canada

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Sponsor information

Organisation

McMaster University (Canada)

ROR

<https://ror.org/02fa3aq29>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

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	05/10/2004		Yes	No