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Premedication for intubation in neonates: a randomised controlled trial

Submission date	Recruitment status	[_] Prospectively registered
19/10/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/10/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

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 measure

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 Sp02 < 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.

Secondary outcome measures
1. Duration of the procedure
2. Duration of hypoxemia (Sp02 < 85%)
3. Number of attempts
4. Maximum change in blood pressure from baseline
5. Occurrence of bradycardia (HR<90/min).

Overall study start date
01/12/1999

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

Age group
Neonate

Sex
Both

Target number of participants
34

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)

Sponsor details
Division of Newborn Medicine
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Sponsor type
University/education

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Not defined

Funder Name
Not provided at time of registration

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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