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Estimating the depth of insertion of oral endotracheal tubes in newborns using weight or vocal cord guide

Submission date
03/09/2013

Recruitment status
No longer recruiting

Registration date
14/10/2013

Overall study status
Completed

Last Edited
21/01/2019

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
Many newborn babies receive help for breathing difficulties after birth. Some of these infants are have a tube (an endotracheal tube - ETT) inserted into their windpipe for support with a ventilator. ETTs have markings at 1cm intervals from the tip so that it is known how far it has been inserted. ETTs also have a marker, the vocal cord guide, 2.5 3cm from the tip. It is important that the ETT is inserted far enough so that it is within the windpipe, but not too far so that the lungs are not ventilated evenly. The position of the ETT tip is confirmed using a chest X-ray. Currently, doctors estimate how far they should insert ETTs in a newborn using a formula based on the babys birth weight. Half of the ETTs are not in the correct position when the insertion depth is estimated using this method. It may be more accurate to use the vocal cord guide. We aim to determine whether estimating the insertion depth of ETTs in newborns with the vocal cord guide, compared to weight, results in more correctly-placed ETTs on chest X-rays.

Who can participate?
Newborn infants who are being intubated (tube inserted) in the Neonatal Intensive Care Unit (NICU) can participate in the study.

What does the study involve?
Newborns are randomly allocated to one of two groups: estimation of ETT insertion depth using the weight-based formula or the vocal cord guide. Correct position of the ETT insertion is found using an X-ray by a specialist.

What are the possible benefits and risks of participating?
Infants will not have additional investigations or treatments by virtue of their participation in the study.
There are no risks in participating above those that already exist due to intubation in an intensive care.

Where is the study run from?
The study is run from the National Maternity Hospital, Holles Street, Dublin, Ireland.

When is study starting and how long is it expected to run for?
The study started in September 2013 and is expected to run for 12 months.

Who is funding the study?
The National Childrens Research Centre, Dublin, Ireland.

Who is the main contact?
Dr. Colm ODonnell
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NEDI2001

Study information

Scientific Title
Estimating Neonatal oral Endotracheal tube Depth of Insertion using weight or vocal cord guide

Acronym
NEDI2

Study objectives

Estimating the appropriate depth of insertion of oral endotracheal tubes (ETT) in newborns using the vocal cord guide is more accurate than using a weight based formula.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at the National Maternity Hospital, Dublin, Ireland; 25/06/2013

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Neonatal intensive care, respiratory support, mechanical ventilation

Interventions
Newborns are randomised to two groups:
1. Oral ETT insertion depth estimated using a weight-basd formula [insertion depth (cm) = 6 + birth weight (kg)]
2. Operators assessment that the top of the vocal cord guide is still visible

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Correct position of the ETT on chest X-ray defined as between the upper border of the first thoracic vertebra (T1) and the lower border of the second thoracic vertebra (T2) on chest X-ray. ETT position will be determined by a consultant paediatric radiologist who will be unaware of the infants treatment allocation.

Secondary outcome measures

1. Number of extubations before chest X-ray
2. Repositioning of ETT following chest X-ray
3. Unequal lung expansion on initial chest X-ray following intubation
4. Air leaks - pneumothorax, pneumomediastinum, pulmonary interstitial emphysema
5. Duration of ventilation
6. Oxygen therapy at 28 days
7. Oxygen at 36 weeks
8. Death before discharge from hospital

Overall study start date
16/09/2013

Completion date
30/06/2014

Eligibility

Key inclusion criteria
Newborn infants intubated in the neonatal intensive care unit (NICU)

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
116

Key exclusion criteria
Infants with upper airway anomalies (e.g. Pierre-Robin sequence) or lung abnormalities (e.g. congenital diaphragmatic hernia) that may distort the upper airway anatomy and alter the position of the ETT tip on chest X-ray (CXR) are not eligible for inclusion.

Date of first enrolment
16/09/2013

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Ireland

Study participating centre
Neonatal Intensive Care Unit
Dublin
Ireland
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Sponsor information

Organisation
The National Maternity Hospital (Ireland)

Sponsor details
c/o Colm O'Donnell
Neonatal Intensive Care Unit
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Research organisation

Funder Name
National Children's Research Centre, Dublin (Ireland)

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	01/07/2018	21/01/2019	Yes	No