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Comparing the use of gestational age or weight to estimate Neonatal Endotracheal tube Depth of Insertion (NEDI)

Submission date
21/02/2012

Recruitment status
No longer recruiting

Registration date
12/06/2012

Overall study status
Completed

Last Edited
17/01/2019

Condition category
Respiratory

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

Plain English summary of protocol

Background and study aims
Newborn babies who have difficulty breathing after birth are often supported with a ventilator (respirator). Babies are ventilated through a plastic tube called an endotracheal tube (ETT) which is inserted into the trachea (windpipe) through the mouth. ETTs are marked each centimetre along their length from the tip so that it is known how far from the baby's lips the tube has been inserted. It is important that the tip of the ETT is correctly positioned in the trachea above the carina (the point where it divides to supply the left and right lung) so that support is given evenly to both lungs. Most doctors estimate how far they should insert the ETT using the baby's weight. Studies suggest that estimating the depth of insertion using their gestational age may be more accurate. We aim to determine which method is more accurate.

Who can participate?
Newborn babies who are having an ETT inserted for respiratory support in the Neonatal Intensive Care Unit (NICU).

What does the study involve?
Babies enrolled in this study will have the depth of insertion of the ETT estimated using either their gestational age or their birth weight.

What are the possible benefits and risks of participating?
One group may have a higher proportion of correctly placed ETTs. There are no more risks above those inherent in needing intubation and ventilation

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

When is study starting and how long is it expected to run for?
The study started on 10/01/2012 and we estimate that it will run for 1 year.

Who is funding the study?
National Children's Research Centre (Ireland)

Who is the main contact?
Dr Colm ODonnell

Contact information

Type(s)
Scientific

Contact name
Dr Colm O'Donnell

Contact details
The National Maternity Hospital
Holles Street
Dublin
Ireland
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial comparing the use of gestational age or weight to estimate Neonatal Endotracheal tube Depth of Insertion (NEDI)

Acronym
NEDI

Study objectives
Compared to using a newborn infant's weight, using the gestational age to estimate the appropriate depth of insertion of an oral endotracheal tube (ETT) will result in more correctly placed ETTs on chest X-ray (i.e. tip of ETT between upper border of the first thoracic vertebra, T1, and the lower border of the second thoracic vertebra, T2)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at The National Maternity Hospital, Holles Street, Dublin, Ireland, 30/11/2011, ref: NEDI001

Study design
Single centre randomised trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Neonatal respiratory support

Interventions
Infants in both treatment arms will have an endotracheal tube placed via the mouth

Infants randomised to WEIGHT will have the ETT secured at the lips at a depth determined by the formula Insertion Depth (cm) = 6 + (birth weight, kg)

Infants randomised to GESTATIONAL AGE will have the ETT secured at the lips at a depth determined by the following table
ETT length at lip (cm) Corrected gestation (weeks)
5.5 23 24
6.0 25 26
6.5 27 29
7.0 30 32
7.5 33 34
8.0 35 37
8.5 38 40
9.0 41 43

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

Endotracheal tube (ETT) tip between the upper border of the 1st thoracic vertebra (T1) and the lower border of the second thoracic vertebra (T2) on chest X-ray

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
10/01/2012

Completion date
30/09/2012

Eligibility

Key inclusion criteria
Newly born infants [term (> or = 37 weeks' gestation) or preterm (< 37 weeks' gestation)] who are intubated in the neonatal intensive care unit

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
90

Key exclusion criteria
Infants with known upper airway (e.g. Pierre-Robin sequence) or lung (congenital diaphragmatic hernia) anomalies

Date of first enrolment
10/01/2012

Date of final enrolment
30/09/2012

Locations

Countries of recruitment

Ireland

Study participating centre
The National Maternity Hospital
Dublin
Ireland
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Sponsor information

Organisation
The National Maternity Hospital (Ireland)

Sponsor details
c/o Dr Colm O'Donnell
Holles Street
Dublin
Ireland
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Children's Research Centre (Ireland)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

The datasets generated and analysed in this study are available upon request from Prof. Colm O' Donnell for a period of 5 years. Consent for sharing this data from the participants' parent(s) /guardian(s) was not specifically sought at the time of study entry. The decision whether to share anonymised data will be made based on a description of the purpose for which the data is sought, and the types of planned analyses

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015	16/01/2019	Yes	No