

Estimating neonatal oral endotracheal tube depth of insertion using weight or suprasternal palpation of the tip

Submission date 15/11/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 01/12/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/06/2020	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data

Plain English Summary

Background and study aims

Many newborn babies have breathing difficulties after birth and need help. Some infants require a plastic tube (called an endotracheal tube) to be inserted into their windpipe (trachea) that is then connected to a breathing machine (ventilator). Endotracheal tubes are inserted through the baby's mouth into their windpipe. It is important that the tip of the tube is in the correct position so that both lungs are ventilated equally. When doctors are inserting the tube, they usually estimate how far the tube needs to be inserted by using the birth weight of the baby. After the tube is inserted, it is secured and a chest x-ray is done to show the tube position. When the distance to which the tube is inserted is estimated using the baby's weight it is in the correct position about 50% of the time. The aim of this study is to find out whether using a different technique to judge the depth of insertion, by gently pressing on the V-shaped notch above the breastbone and feeling the tube as it passes under one's finger, would lead to more tubes being better placed.

Who can participate?

Newborn babies who are intubated in the neonatal intensive care unit (NICU)

What does the study involve?

Babies are randomly allocated to have the depth to which the endotracheal tube is inserted estimated either by feeling the tip of the tube or by using their birth weight. All babies have the endotracheal tube position checked with a chest X-ray. Babies do not undergo any extra tests for this study.

What are the possible benefits and risks of participating?

One method of estimating the insertion depth may be better, but this will not be known until the study has finished and the results have been analysed. There are no known extra risks of taking part in the study.

Where is the study run from?

National Maternity Hospital (Ireland)

When is the study starting and how long is it expected to run for?
December 2016 to June 2019

Who is funding the study?
National Maternity Hospital (Ireland)

Who is the main contact?
1. Prof. Colm O'Donnell
2. Dr Madeleine Murphy

Contact information

Type(s)
Scientific

Contact name
Prof Colm O'Donnell

Contact details
Neonatal Unit
National Maternity Hospital
Holles Street
Dublin
Ireland
D02 YH21

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NEDI31

Study information

Scientific Title
Estimating neonatal oral endotracheal tube depth of insertion using weight or suprasternal palpation of the tip: a randomised controlled trial

Acronym
NEDI 3

Study hypothesis

Estimating the appropriate depth of insertion of oral endotracheal tubes in newborns using palpation of the tip of the endotracheal tube in the suprasternal notch is more accurate than using a weight based formula.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee, National Maternity Hospital, 14/11/2016, ref: EC 34.2016

Study design

Single-centre unmasked randomised controlled 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 contact details to request a participant information sheet

Condition

Endotracheal intubation of the newborn infant

Interventions

Infants who are intubated in the neonatal intensive care unit (NICU) will be randomised using sequentially numbered sealed opaque envelopes to have the depth of insertion estimated using:

1. Intervention: suprasternal palpation of the endotracheal tube (ETT) tip
2. Control: weight-based formula [insertion depth (cm) = weight (kg) + 6]

All babies will have the ETT position checked with a chest X-ray.

Intervention Type

Procedure/Surgery

Primary outcome measure

ETT tip in correct position (between upper border of T1 and lower border of T2) on chest X-ray (CXR) taken to confirm position immediately after intubation

Secondary outcome measures

1. ETT tip above T1 on CXR taken to confirm position immediately after intubation
2. ETT tip below T2 on CXR taken to confirm position immediately after intubation

3. Number of extubations before CXR
4. Repositioning of ETT following CXR
5. Air leaks (pneumothorax, pneumomediastinum, pulmonary interstitial emphysema) occurring before hospital discharge (will vary for participants, usually depending on gestational age at birth)
6. Duration of ventilation, assessed before hospital discharge
7. Oxygen therapy at 28 days of life
8. Oxygen therapy at 36 weeks corrected gestational age
9. Death before discharge from hospital

Overall study start date

01/12/2016

Overall study end date

30/06/2019

Eligibility

Participant inclusion criteria

Newborn infants of any gestational age and either gender intubated in NICU

Participant type(s)

Patient

Age group

Neonate

Sex

Both

Target number of participants

116

Total final enrolment

118

Participant 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 CXR

Recruitment start date

02/12/2016

Recruitment end date

31/12/2018

Locations

Countries of recruitment

Ireland

Study participating centre
National Maternity Hospital
Holles Street
Dublin
Ireland
D02 YH21

Sponsor information

Organisation
National Maternity Hospital

Sponsor details
Neonatal Unit
Holles Street
Dublin
Ireland
D02 YH21

Sponsor type
Hospital/treatment centre

ROR
<https://ror.org/03jcxa214>

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
National Maternity Hospital

Results and Publications

Publication and dissemination plan

Findings will be presented at international scientific conferences (e.g. European Society for Paediatric Research, Pediatric Academic Societies) before submitting them in a manuscript for publication at a peer-reviewed scientific journal.

Intention to publish date

30/06/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Prof. Colm O'Donnell.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2020	09/06/2020	Yes	No