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The NORD trial: Needle aspiration OR chest Drain insertion for pneumothorax in newborns

Submission date
23/07/2013

Recruitment status
No longer recruiting

Registration date
15/08/2013

Overall study status
Completed

Last Edited
30/05/2018

Condition category
Neonatal Diseases

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

Plain English summary of protocol

Background and study aims
Many babies have difficulty breathing after birth. Some of these babies have air collected between their chest wall and the outer surface of the lung. This collection of air is called a pneumothorax. If doctors believe that a pneumothorax is making it difficult for babies to breathe, they remove the air. Most doctors do this by inserting a drain through the chest wall and leaving it in place. Some doctors insert a needle to suck out the air which they then remove. Many infants who have their pneumothorax removed with a needle go on to have a chest drain inserted. It is not known whether it is preferable to do the chest drain immediately or to attempt needle insertion. In this study, we will find this out.

Who can participate?
Newborn babies who are receiving breathing support and have pneumothorax

What does the study involve?
Babies will be randomly allocated to have their pneumothorax drained either by needle aspiration or with a chest drain. We will determine how many infants in both groups ultimately have a chest drain insertion. All babies will be followed up until they get discharged from the hospital.

What are the possible benefits and risks of participating?
Both needle aspiration and chest drain insertion are well-accepted methods of draining a pneumothorax. There are no additional risks (above those already encountered by a baby who is receiving breathing support and who is having a pneumothorax drained) by participating in the study. Babies will not have additional tests because they are participating in the study. Fewer infants may have chest drains inserted by participating in the study.

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

When is the study starting and how long is it expected to run for?
The study starts in August 2013 and is expected to last for one year

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

Protocol serial number
NVD001

Study information

Scientific Title
A randomised controlled trial of needle aspiration or chest drain insertion for pneumothorax in newborns

Acronym
NORD

Study objectives
In newborn infants with symptomatic pneumothoraces, aspirating air with a needle reduces the need for chest drain insertion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at the National Maternity Hospital, Dublin, 04/06/2013

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pneumothorax in newborn infants

Interventions
Aspiration with a 23 or 25 gauge "butterfly" needle and 20mL syringe versus chest drain insertion.
Acute intervention (up to 15 minutes). Follow-up until hospital discharge.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Chest drain insertion for management of pneumothorax on chest x-ray within 6 hours of diagnosis.

Key secondary outcome(s))
1. Duration of chest drain
2. Number of chest drain insertions
3. Duration of ventilation post intervention
4. Duration of ventilation
5. Duration of nasal continuous positive airway pressure
6. Duration of supplemental oxygen
7. Bronchopulmonary dysplasia oxygen treatment at 28 days
8. Chronic lung disease oxygen treatment at 36 weeks post menstrual age
9. Nosocomial infections
10. Pleural effusions
11. Duration of hospital stay
12. Death before discharge from hospital

Completion date
30/06/2014

Eligibility

Key inclusion criteria
Infants (term and preterm) will be eligible for enrolment in the study if they
1. Have a pneumothorax diagnosed on chest x-ray by treating clinicians
2. Are receiving respiratory support
2.1. Mechanical ventilation (conventional or high frequency oscillation)

2.2. Continuous positive airway pressure (CPAP)
2.3. Supplemental oxygen FiO2 > 40% by head box or nasal cannulae to keep SpO2 >90%
3. The treating clinicians deem the pneumothorax requires treatment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
Infants will be excluded from the study if they:
1. Do not have respiratory distress
2. Have significant pulmonary hypoplasia, e.g. Potter's sequence

Date of first enrolment
19/08/2013

Date of final enrolment
30/06/2014

Locations

Countries of recruitment
Australia

Germany

Ireland

Italy

Netherlands

Norway

Sweden

Study participating centre
The National Maternity Hospital
Dublin
Ireland
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Sponsor information

Organisation
The National Maternity Hospital (Ireland)

ROR
https://ror.org/03jcxa214

Funder(s)

Funder type
Research organisation

Funder Name
National Children's Research Centre (Ireland)

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	01/07/2018		Yes	No