

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

<b>Submission date</b> 23/07/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/08/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/05/2018	<b>Condition category</b> Neonatal Diseases	<input type="checkbox"/> 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 O'Donnell  
codonnell@nmh.ie

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Colm O'Donnell

**Contact details**  
Neonatal Intensive Care Unit  
The National Maternity Hospital  
Holles Street  
Dublin  
Ireland  
2  
-  
codonnell@nmh.ie

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

**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**

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 measure**

Chest drain insertion for management of pneumothorax on chest x-ray within 6 hours of diagnosis.

**Secondary outcome measures**

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

**Overall study start date**

19/08/2013

**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  $FiO_2 > 40\%$  by head box or nasal cannulae to keep  $SpO_2 > 90\%$
- 3. The treating clinicians deem the pneumothorax requires treatment

**Participant type(s)**

Patient

**Age group**

Neonate

**Sex**

Both

**Target number of participants**

70

**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)

**Sponsor details**  
c/o Colm O'Donnell  
Neonatal Intensive Care Unit  
Holles Street  
Dublin  
Ireland  
2

**Sponsor type**  
Hospital/treatment centre

**Website**  
<http://www.nmh.ie/>

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

## **Funder(s)**

**Funder type**  
Research organisation

**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****IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2018		Yes	No