

# Neonatal ventilation with INhaled Nitric Oxide versus Ventilatory support withOut inhaled nitric oxide for severe respiratory failure: a randomised controlled trial

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| <b>Submission date</b><br>25/10/2000   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>25/10/2000 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>01/09/2022       | <b>Condition category</b><br>Neonatal Diseases    | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input checked="" type="checkbox"/> Results          |
|  |   | <input type="checkbox"/> Individual participant data |

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
G9608436

## Study information

**Scientific Title**

Neonatal ventilation with INhaled Nitric Oxide versus Ventilatory support withOut inhaled nitric oxide for severe respiratory failure: a randomised controlled trial

**Acronym**

The INNOVO Trial

**Study objectives**

Although inhaled nitric oxide (INO) may be a promising treatment for newborn infants with severe respiratory failure, the results from three previous small trials were inconclusive. The objectives are:

1. To assess the clinical effectiveness and cost effectiveness of a policy of adding or not adding inhaled nitric oxide (INO) to the ventilator gases of neonates with severe respiratory failure
2. To conduct relevant sub-studies

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Respiratory disease

**Interventions**

Nitric oxide/control

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Inhaled nitric oxide (INO)

**Primary outcome(s)**

1. To conduct relevant sub-studies
2. Death
3. Severe disability at 1 year of age (corrected)
4. Chronic lung disease, defined as being on supplemental oxygen at the expected date of

delivery (preterm stratum) and at 28 days post delivery ('mature stratum')

5. Length of time on supplemental oxygen

6. Costs

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

31/07/2005

## Eligibility

**Key inclusion criteria**

1. Respiratory failure requiring ventilatory support

2. Less than 28 days old

3. No evidence of uncorrected bleeding disorder

4. No ultrasound evidence of intraparenchymal lesions

5. No contra-indication to continuation of treatment, known at trial entry

6. Informed assent of the parent(s) following discussion and written information

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Neonate

**Sex**

All

**Key exclusion criteria**

Does not comply with above criteria

**Date of first enrolment**

01/02/1997

**Date of final enrolment**

31/07/2005

## Locations

**Countries of recruitment**

United Kingdom

England

Ireland

**Study participating centre**  
**Medical Statistics Unit**  
London  
United Kingdom  
WC1E 7HT

## Sponsor information

**Organisation**  
Medical Research Council (MRC) (UK)

## Funder(s)

**Funder type**  
Research council

**Funder Name**  
Medical Research Council (UK)

**Alternative Name(s)**  
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**  
Not provided at time of registration

**IPD sharing plan summary**  
Not provided at time of registration

**Study outputs**

| <b>Output type</b>              | <b>Details</b> | <b>Date created</b> | <b>Date added</b> | <b>Peer reviewed?</b> | <b>Patient-facing?</b> |
|---------------------------------|----------------|---------------------|-------------------|-----------------------|------------------------|
| <a href="#">Results article</a> |                | 01/04/2005          |                   | Yes                   | No                     |
| <a href="#">Results article</a> |                | 01/04/2007          |                   | Yes                   | No                     |
| <a href="#">Results article</a> |                | 01/11/2008          |                   | Yes                   | No                     |
| <a href="#">Study website</a>   | Study website  | 11/11/2025          | 11/11/2025        | No                    | Yes                    |