

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

Submission date 25/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 25/10/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 01/09/2022	Condition category 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

Contact name

Prof Diana Elbourne

Contact details

Medical Statistics Unit
London School of Hygiene and Tropical Medicine
Keppel Street
London
United Kingdom
WC1E 7HT
+44 (0)20 7927 2629
diana.elbourne@lshtm.ac.uk

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

Primary study design

Interventional

Study design

Randomised controlled trial

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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/04/2005		Yes	No
Results article		01/04/2007		Yes	No
Results article		01/11/2008		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes