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

Submission date	Recruitment status No longer recruiting Overall study status	Prospectively registered	
25/10/2000		☐ Protocol	
Registration date		Statistical analysis plan	
25/10/2000	Completed	[X] Results	
Last Edited 01/09/2022	Condition category Neonatal Diseases	[] Individual participant data	

Plain English summary of protocol

Not provided at time of registration

Study website

http://www.innovo-trial.org.uk

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

- 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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/02/1997

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

Age group

Neonate

Sex

Both

Target number of participants

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

England

Ireland

United Kingdom

Study participating centre Medical Statistics Unit

London United Kingdom WC1E 7HT

Sponsor information

Organisation

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent London United Kingdom W1B 1AL +44 (0)20 7636 5422 clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

http://www.mrc.ac.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, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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