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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 25/10/2000	**Overall study status** Completed	
Last Edited 01/09/2022	**Condition category** Neonatal Diseases	

Plain English summary of protocol
Not provided at time of registration

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

Contact information

Type(s)
Scientific

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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

160

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)

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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