

Validation of analgesic effect of nitrous oxide in neonates and infants

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/10/2016	Condition category Neonatal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
N0060055834

Study information

Scientific Title
Validation of analgesic effect of nitrous oxide in neonates and infants

Study objectives

The purpose of this research is to validate the analgesic effect of nitrous oxide (N₂O) in neonates and infants.

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

Neonatal and infant analgesia

Interventions

Prospectively randomised, placebo-controlled, clinical trial. Patients randomised to:

1. Nitrous oxide
2. Placebo

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Nitrous oxide

Primary outcome(s)

1. Neonatal pain assessment tool (developed by Keeble and Twaddle [1995])
2. Physiologic parameters:
 - 2.1. Blood pressure
 - 2.2. Heart rate
 - 2.3. Respiratory rate
 - 2.4. Oxygen saturation

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/10/2005

Eligibility

Key inclusion criteria

1. Pre-term newborns (32 - 37 weeks), n = 90
2. Full-term newborns (38 - 42 weeks), n = 90
3. Infants (1 - 3 months), n = 90

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/05/2000

Date of final enrolment

31/10/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Chelsea & Westminster Hospital

London

United Kingdom

SW10 9NH

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

University/education

Funder Name

Chelsea and Westminster NHS Foundation Trust (UK) - NHS R&D Support Funding

Funder Name

Imperial College School of Medicine (ICSM) (UK) - Research Funds

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration