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Validation of analgesic effect of nitrous oxide in neonates and infants

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 18/10/2016	**Condition category** Neonatal Diseases	

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 (N20) 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