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# Validation of analgesic effect of nitrous oxide in neonates and infants

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

### 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 measure
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

### Secondary outcome measures
Not provided at time of registration

### Overall study start date
01/05/2000

### 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

### Age group
Neonate

### Sex
Both

### Target number of participants
270

### 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
England

United Kingdom

**Study participating centre**
**Chelsea & Westminster Hospital**
London
United Kingdom
SW10 9NH

# Sponsor information

**Organisation**
Department of Health

**Sponsor details**
Richmond House
79 Whitehall
London
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**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# 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

## Publication and dissemination plan
Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary
Not provided at time of registration