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

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

### Plain English summary of protocol

Not provided at time of registration

# Contact information

### Type(s)

Scientific

#### Contact name

Prof Mervyn Maze

### Contact details

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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 United Kingdom SW1A 2NL

### 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