

# A comparison of sevoflurane and nitrous oxide as inhalation agents for dental sedation

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<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/03/2020	<b>Condition category</b> Oral Health	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N0013122021

# Study information

## Scientific Title

A comparison of sevoflurane and nitrous oxide as inhalation agents for dental sedation

## Study objectives

To assess whether sevoflurane/oxygen is a suitable alternative to nitrous oxide/oxygen sedation in the treatment of anxious adult dental patients presenting to a sedation clinic in a dental hospital.

## 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

Oral Health: Anaesthesia/Sedation

## Interventions

The level of patient's anxiety will be assessed then each patient will attend for two visits. On the first visit, patients will be given either nitrous oxide/oxygen or sevoflurane/oxygen, the choice being randomized. Patients will be given the alternative drug on the second visit. The operator will score the acceptability of sedation received. After a period of recovery, the patient will be asked to fill in a questionnaire about their experience of sedation.

## Intervention Type

Drug

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Sevoflurane and nitrous oxide

### **Primary outcome measure**

The patient's vital signs will be recorded throughout the procedure and analysed and compared for the two sedative agents. This will give an indication of whether sevoflurane is a more acceptable agent for sedation both in terms of the operator and the patient.

### **Secondary outcome measures**

Not provided at time of registration

### **Overall study start date**

01/04/2002

### **Completion date**

31/07/2003

## **Eligibility**

### **Key inclusion criteria**

1. Adult who have some form of dental anxiety
2. American Society of Anesthesiologists (ASA) I/II
3. Can give valid consent.

Patients must be escorted by a responsible adult on the days of the sedation procedures.

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Not Specified

### **Target number of participants**

25 patients to be selected from the dental hospital sedation clinic.

### **Key exclusion criteria**

- 1 Pregnancy or possible pregnancy
- 2 Nursing mothers
3. Patients with heart conditions
4. History of allergy to sevoflurane or any related agents

### **Date of first enrolment**

01/04/2002

### **Date of final enrolment**

31/07/2003

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Guy's Hospital**

London

United Kingdom

SE1 9RT

**Sponsor information****Organisation**

Department of Health (UK)

**Sponsor details**

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

**Sponsor type**

Government

**Website**

<http://www.doh.gov.uk>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Guy's and St Thomas' NHS Foundation Trust

**Alternative Name(s)****Funding Body Type**

Government organisation

**Funding Body Subtype**

Local 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****IPD sharing plan summary**

Not provided at time of registration