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

Submission date	Recruitment status	[ ] Prospectively registered
12/09/2003	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
12/09/2003	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/03/2020	Oral Health	[ ] 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