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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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Guy's Hospital
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Department of Health (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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration