ISRCTN88442975 https://doi.org/10.1186/ISRCTN88442975

Nitrous Oxide Sedation: How Long Must People Really Avoid Their Normal Activities

Submission date 10/05/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/05/2004	**Overall study status** Completed	
Last Edited 31/08/2011	**Condition category** Surgery	

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
8098

Study information

Scientific Title

Acronym
Nitrous Oxide Sedation

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Provided by University Institutional Review Board.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Sedation

Interventions
On three separate occasions, volunteers (N=12) received 100% oxygen or 20% or 40% N2O for 30 min. Dependent measures included the multiple sleep latency test (MSLT), a Drug Effects /Liking questionnaire, visual analogue scales, and five psychomotor tests.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Nitrous Oxide

Primary outcome measure

Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2003

Completion date
30/06/2003

Eligibility

Key inclusion criteria
Candidates who stated they were healthy, non-smoking, age 21-35 years, within 30% of ideal body weight and had normal sleeping habits were scheduled for a screening interview. Urine pregnancy tests were performed to ensure that female subjects were not pregnant. Subjects were asked to avoid depressants including ethanol (confirmed by measuring exhaled ethanol) and stimulants for 24 hours before study sessions. Subjects were formally admitted to the study if, after sleep latency testing, their average sleep latency was 10 min and they had no onsets of rapid eye movement (REM) sleep, which is indicative of narcolepsy.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
12

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2003

Date of final enrolment
30/06/2003

Locations

Countries of recruitment
United States of America

Study participating centre
Department of Anesthesia
Iowa City, IA
United States of America
52242

Sponsor information

Organisation
The University of Chicago (USA)

Sponsor details
Department of Anesthesia
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Chicago, IL
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60637
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Sponsor type
University/education

Website
http://www.uchicago.edu/

ROR
https://ror.org/024mw5h28

Funder(s)

Funder type
Research organisation

Funder Name
NIH (GCRC at the University of Chicago, funded by grant number M01 RR00055 from the National Center for Research Resources of the National Institutes of Health) and the Department of Anesthesia, University of Chicago

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	12/05/2004		Yes	No