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Randomised Controlled Trial of sedation for colonoscopy: Entonox versus Midazolam /Fentanyl

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 25/06/2010	**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

N0084160165

Study information

Scientific Title

Study objectives
Does nitrous oxide (Entonox) provide better pain relief than the conventional intravenous sedation during colonoscopy

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)
Diagnostic

Participant information sheet

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

Interventions
Prospective randomised controlled study. Pilot study initially involving 100 patients to determine statistical power.
Pts will be randomised using the sealed envelope method of block randomisation. Patients randomised to the entonox group will be taught methods of use. Patients will be shown the visual analogue score for pain and asked to mark them.
Those randomised to conventional intravenous sedation will be informed of same and will undergo colonoscopy using standard intravenous sedation protocols.
Entonox group encouraged to inhale the nitrous oxide for a full 60 seconds initially and then as and when required throughout procedure. Post colonoscopy both groups will be asked to indicate pain using visual analogue scale in the recovery.

Intervention Type

Procedure/Surgery

Phase
Phase IV

Primary outcome measure
Pain score assessed by VAS

Secondary outcome measures
Not provided at time of registration

Overall study start date
11/03/2005

Completion date
10/02/2006

Eligibility

Key inclusion criteria
All patients undergoing elective colonoscopy would be prospective participants.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. History of chronic respiratory disease
2. History of colonic resection
3. Intolerance to the drugs
4. Patients with pre-existing adbominal or perianal pain
5. Unwilling participants

Date of first enrolment
11/03/2005

Date of final enrolment
10/02/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Acadmemic Surgical Unit
Hull
United Kingdom
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
The North and South Bank Research and Development Consortium (UK) - NHS R&D Support Funding

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?
Abstract results	conference proceedings	01/04/2009		No	No