

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

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 25/06/2010	Condition category Surgery	<input type="checkbox"/> Individual participant data

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

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

Study type(s)

Diagnostic

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(s)

Pain score assessed by VAS

Key secondary outcome(s))

Not provided at time of registration

Completion date

10/02/2006

Eligibility

Key inclusion criteria

All patients undergoing elective colonoscopy would be prospective participants.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

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

Date of first enrolment

11/03/2005

Date of final enrolment

10/02/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Academic Surgical Unit

Hull

United Kingdom

HU16 5JQ

Sponsor information

Organisation

Department of Health

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**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