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Randomised controlled trial of patient controlled sedation for colonoscopy: entonox vs target controlled infusion of propofol

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 24/04/2012	**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

Protocol serial number
N0084178528

Study information

Scientific Title

Study objectives

Does patient controlled sedation using target controlled infusion of propofol provide an effective pain relief as that using entonox?

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
Surgery: Analgesia

Interventions
Prospective RCT involving all patients undergoing elective colonoscopy at the Endoscopy Suite, Castle Hill Hospital.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
entonox, propofol

Primary outcome(s)
Pain score on the visual analogue scale

Key secondary outcome(s))
Patient comfort, completion rate, time taken and complications, time to discharge and time for return of psychomotor function.

Completion date
30/10/2006

Eligibility

Key inclusion criteria
All patients of both sexes undergoing elective colonoscopy will be recruited.

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
Patients with chronic pulmonary disease, history of colonic resection, intolerance to any of the drugs, unwilling to enter trial, ASA class IV, allergy to soybeans, eggs, history of seizure disorder, sleep apnoea, or difficult intubation, a short thin neck or the inability to open mouth widely.

Date of first enrolment
18/10/2005

Date of final enrolment
30/10/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Castle Hill Hospital
Cottingham
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - 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?
Results article	results	01/01/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes