

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
Registration date 28/09/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 24/04/2012	Condition category Surgery	☐ 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
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