ISRCTN65879800 https://doi.org/10.1186/ISRCTN65879800

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

Contact name
Mr Sushil Maslekar

Contact details
Castle Hill Hospital
Castle Road
Cottingham
United Kingdom
HU16 5JQ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Pain score on the visual analogue scale

Secondary outcome measures
Patient comfort, completion rate, time taken and complications, time to discharge and time for return of psychomotor function.

Overall study start date
18/10/2005

Completion date
30/10/2006

Eligibility

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

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
20

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

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?
Results article	results	01/01/2011		Yes	No