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

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

### Primary study design
Interventional

### Study design
Randomised controlled trial

### 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 |