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# A comparison of midazolam with fentanyl or pethidine as a sedation for colonoscopy.

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 30/09/2005 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 30/09/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 12/04/2011 | Surgery | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N0649155306

# Study information

### Scientific Title

### Study objectives
Is there a significant difference between midazolam + fentanyl or midazolam + pethidine for colonoscopy sedation in terms of discomfort experienced by patients.

### 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)
Not Specified

### Participant information sheet

### Health condition(s) or problem(s) studied
Surgery: Colonoscopy

### Interventions
Patients must receive sedation for colonoscopy. They will be randomised to receive one of the two drug combinations, both of which are already used in this Trust. There will be no cost, safety or training implications, as the study will use existing practice and protocols. Data will be collected to compare efficacy, safety and acceptability of the two combinations.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
midazolam, fentanyl, pethidine

### Primary outcome measure
1. Patient pain experienced/recalled
2. Comparison between two sedation regimes

### Secondary outcome measures
1. Experience of pain related to Endoscopist
2. Patient expectation pre-endoscopy
3. Friendliness of staff
4. Incidence of adverse events during endoscopy
5. Need for more sedative
6. Desaturation
7. Agitation
8. Time taken for endoscopy (completion rate)
9. Time taken for recovery
10. Does patient's perception differ from Endoscopist, Nurse?

### Overall study start date
20/02/2005

### Completion date
31/12/2006

## Eligibility

### Key inclusion criteria
All patients attending for colonoscopy (approx 2000 per year) will be eligible.

### Participant type(s)
Patient

### Age group
Not Specified

### Sex
Not Specified

### Target number of participants
2000

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
20/02/2005

### Date of final enrolment
31/12/2006

## Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Consultant Gastroenetrologist**
London
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# Sponsor information

**Organisation**
Department of Health

**Sponsor details**
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**Sponsor type**
Government

**Website**
http://www.dh.gov.uk/Home/fs/en

# Funder(s)

**Funder type**
Government

**Funder Name**
Queen Elizabeth Hospital NHS Trust (UK)

# 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 | 01/03/2009 | | Yes | No |