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

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

Study type(s)
Not Specified

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(s)
1. Patient pain experienced/recalled
2. Comparison between two sedation regimes

Key secondary outcome(s))
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?

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Consultant Gastroenetrologist
London
United Kingdom
SE18 4QH

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Queen Elizabeth Hospital NHS Trust (UK)

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	01/03/2009		Yes	No