

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

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/04/2011	Condition category Surgery	<input type="checkbox"/> 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

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 Gastroenterologist

London

United Kingdom

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Sponsor information

Organisation

Department of Health

Sponsor details

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79 Whitehall

London

United Kingdom

SW1A 2NL

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dhmail@doh.gsi.org.uk

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