

Deep sedation compared with moderate sedation in polyp detection during colonoscopy

Submission date 26/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 26/08/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 26/08/2010	Condition category Surgery	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Deep sedation compared with moderate sedation in polyp detection during colonoscopy: a randomised controlled trial

Study objectives
We sought to compare the performance of colonoscopy for the detection of polyps in patients sedated with deep sedation and moderate sedation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Venizelion Ethics Committee approved on the 4th March 2010 (ref: 2517)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Sedation/colonoscopy

Interventions

Patients in both groups initially received intravenously (IV) 2 mg (less than 70 kg body weight [b. w.]) or 3 mg (greater than 70 kg b.w.) of midazolam and 25 mg of pethidine. Additional midazolam was carefully titrated in boluses of 1 mg IV to achieve the desired level of sedation, moderate or deep according to the randomisation. Bolus doses of 25 mg pethidine were also given if patients complained of pain or if there were other indications of pain such as facial grimaces, movement and a sudden increase in heart rate.

All colonoscopies were performed with wide-angle (170°), high-resolution videocolonoscopes:

1. Olympus (CFH180AL, Tokyo, Japan) with a high-definition 1080-line screen
2. Olympus (OEV191H, Tokyo, Japan) and video processor Olympus (EVIS EXERA II CV-180, Tokyo, Japan)

Patients were treated with sedatives during the procedure (colonoscopy), which lasted from 15 to 45 min approximately for every patient. There wasn't follow up for any arm of our trial.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

Polyp detection rate, measured at end of study

Key secondary outcome(s)

Measured at end of study:

1. Patients' and the endoscopists satisfaction
2. Recovery time
3. Adverse events related to sedation

Completion date

15/10/2009

Eligibility

Key inclusion criteria

1. Patients aged 50 years and older, either sex
2. Undergoing colonoscopy for colorectal cancer (CRC) screening, postpolypectomy surveillance, or other indications for which the primary goal of the examination was detection of neoplasia

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Polyposis syndromes
2. Hereditary nonpolyposis CRC
3. Previous surgical resection of the colon or rectum
4. Active anticoagulation
5. Inflammatory bowel disease
6. Cases with inadequate bowel preparation
7. Incomplete colonoscopy
8. Cases where the desired level of sedation was not achieved or the level of unintended level of deep sedation occurred

Date of first enrolment

06/06/2009

Date of final enrolment

15/10/2009

Locations

Countries of recruitment

Greece

Study participating centre

Knossou Avenue

Heraklion

Greece

71409

Sponsor information

Organisation

Venizelion General Hospital of Heraklion (Greece)

ROR

<https://ror.org/043889z90>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Venizelion General Hospital of Heraklion (Greece)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration