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Deep sedation compared with moderate sedation in polyp detection during colonoscopy

Submission date 26/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 26/08/2010	**Overall study status** Completed	
Last Edited 26/08/2010	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
Polyp detection rate, measured at end of study

Secondary outcome measures
Measured at end of study:
1. Patients' and the endoscopists satisfaction
2. Recovery time
3. Adverse events related to sedation

Overall study start date
06/06/2009

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

Age group
Adult

Sex
Both

Target number of participants
504

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)

Sponsor details
Knossou Avenue
Heraklion
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Sponsor type
Hospital/treatment centre

Website
http://www.venizeleio.gr/

ROR
https://ror.org/043889z90

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Venizelion General Hospital of Heraklion (Greece)

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