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Patient And Gastroenterologists Experience with sedation during colonoscopies

Submission date
14/01/2013

Recruitment status
No longer recruiting

Registration date
23/01/2013

Overall study status
Completed

Last Edited
12/05/2015

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
The number of colonoscopies as screening procedures has increased in recent years and will continue to so in the near future. Patients undergoing such procedures expect safe and comfortable environments. It is not surprising that the number of patients and endoscopists' requests for sedation has also increased.
The aim of our study is to investigate the differences in patient and endoscopist's level of satisfaction and experience and how safe the different sedation methods are.

Who can participate?
Patients undergoing elective diagnostic or therapeutic colonoscopy, over 18 years old.

What does the study involve?
Patients will randomly allocated to three groups for three commonly used sedations. Group 1 will receive sedation with midazolam/fentanyl by gastroenterologist, Group 2 will receive sedation with propofol TCI/ alfentanil by anaesthesia nurse, and Group 3 will receive alfentanil by gastroenterologist. All patients will fill in a questionnaire before and after the procedure. Endoscopists will also have to fill in a questionnaire. Patients will also have to perform the Trieger dot test (combine points with a pen). Patients in all three groups will be monitored in the standard way and will receive a face mask with 2l of oxygen from start of sedation till the end of the endoscopic procedure. Interventions will be monitored using a video assisted camera system. In the recovery room patients will be monitored and will stay for 1 hour. The following day there will a phone interview with another questionnaire about satisfaction.

What are the possible benefits and risks of participating?
The benefits include: answers to as to which form of sedation is most satisfying and safe for patients and improved sedation management for future patients. There are no additional risks of participating.

Where is the study run from?
Academic Medical Centre (AMC), Amsterdam, the Netherlands

When is the study starting and how long is it expected to run for?
The study ran from October 2010 to March 2011.

Who is funding the study?
Internal funding AMC

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2010-020502-15

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Patient And Gastroenterologists Experience with different sedation regimes during colonoscopies

Acronym
PAGE

Study objectives
Opioid only sedation with Alfentanil is as safe as other sedation regimes and results in satisfied patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee Academic Medical Center [Medisch Ethische Toetsingscommissie Academisch Medisch Centrum], 17/06/2010, ref: METC 10/060, NL31863

Study design
Single-center randomized controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Elective colonoscopies for diagnostic or therapeutical interventions

Interventions
The study compares three commonly used strategies for sedation: alfentanil given by endoscopist - will be compared with fentanyl/midazolam based sedation by gastroenterologist and anaesthesia nurse accomplished propofol/alfentanil sedation.

All patients will receive a validated questionnaire to fill in before procedure and perform the Trieger test as a measure of psychomotoric recovery from sedation. Additionally, endoscopists have to fill in a validated questionnaire.

Group 1 will receive sedation with midazolam/fentanyl by gastroenterologist to achieve the targeted sedation score (Observer/Assessment of Alertness/Sedation Scale >=4).

Group 2 will receive sedation with propofol TCI/ alfentanil by anaesthesia nurse to achieve the targeted sedation score (Observer Assessment of Alertness/Sedation OAAS Scale>=4).

Group 3 will receive alfentanil by gastroenterologist to achieve the targeted sedation score (OAAS Scale>=4).

Patients in all three groups will be monitored using SO2, Electrocardiography (ECG), Non-invasive measurement of blood pressure (NIBP) and capnography, reflecting common practice. All patients will receive a face mask with 2 litre of oxygen from start of sedation till the end of the endoscopic procedure.

Interventions will be monitored using a video assisted camera system, which will not only provide an overview over the hole situation (patient, nurse, endoscopist), but also register time adapted SO2, ECG, NIBP and capnography.

At arrival in the recovery room patients will be monitored by pulse oximetry (SO2), ECG and NIBP only.

All patients will stay in the recovery room for 1 hours. At arrival, 30 and 60 min later virtual discharge will be determined based on Aldrete Score.

Ready for discharge will be declared when an Aldrete Score of nine (9) or pre-procedure score is met.

The next day the patient is called at home to answer part 2 of the questionnaire.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Alfentanil, fentanyl, midazolam, propofol

Primary outcome measure
to clarify whether there are differences in experience and satisfaction of patients and endoscopists between different clinically used sedation regimes in patients undergoing colonoscopy?

Main study parameters are the experiences (e.g. satisfaction levels reached) made by patients and gastroenterologist during sedation. These parameters are collected by means of questionnaires before and after the procedure and on the following day.

Secondary outcome measures
Which form of sedation is safer for the patient in regard to respiratory and cardiovascular problems? Surrogate parameters of pulmonary and cardiovascular problems are oxygen saturation (SO2) measured by pulse oximetry, exhaled CO2 (capnography), heart rate, arrhythmias (ECG) and blood pressure (non-invasive blood pressure measurement (NIBP).

Pre procedure
Patient (part 1) and endoscopist: questionnaire
Patient: Trieger Test

Colonoscopy procedure:
Sedation regime 1, 2, or 3
Monitoring using SO2, ECG, NIBP, capnography
Face mask with 2 l O2

Recovery room (post procedure):
Aldrete score (30, 60 min)
30 min

Patient (part 2a) and endoscopist questionnaire
Patient: Trieger Test
60 min
Patient: Trieger Test

Next day:
Interview with patient by phone (part 2 c questionnaire)

Overall study start date
01/10/2010

Completion date
01/04/2011

Eligibility

Key inclusion criteria
The patients must comply with the following criteria in order to be eligible to participate in this clinical study:
1. Age range > 18 years without upper limit, female/male
2. American Society of Anesthesiologists (ASA) classification I - IV
3. Patients, undergoing elective diagnostic or therapeutic colonoscopy.
4. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
180

Key exclusion criteria
1. Age range < 18 years
2. ASA classification V
3. Allergic reaction to planned medication in the patient's medical history
4. Unregulated hypertension
5. Bradycardia
6. Arrhythmia

Date of first enrolment
01/10/2010

Date of final enrolment
01/04/2011

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre
Amsterdam
Netherlands
1100DD

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

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Meibergdreef 9
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1100DD

Sponsor type
Hospital/treatment centre

Website
http://www.amc.nl

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

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	01/08/2014		Yes	No