Patient and gastroenterologists experience with different sedation regimes during colonoscopies (PAGE)

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The aim of the present study is to investigate the differences in patient and endoscopist satisfaction and experiences and patient*s safety with different sedation protocols.

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34691

Source
ToetsingOnline

Brief title
Patient and gastroenterologists experience with sedation

Condition

- Other condition

Synonym
bowel endoscopy, colonoscopie

Health condition

darmstelselaandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: colonoscopy, safety, satisfaction, sedation

Outcome measures

Primary outcome

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. We will also measure heart rate and heart rate variability by Holter ECG as a mark for gastroenterologist stress level during colonoscopy (stress level of an anesthesiologist can not be measured as there is normally no anesthesiologist during these diagnostic procedures).
Further study parameters include in patients measurement of oxygen saturation (SO2) measured by pulseoxymetry, exhaled CO2 (capnography), heart rate, arrhythmias (ECG) and blood pressure (non-invasive blood pressure measurement, NIBP). These parameters are surrogate parameters of pulmonary and cardiovascular problems, experienced by the patient during sedation.

Secondary outcome

not applicable

Study description

Background summary

The number of endoscopic gastroenterological procedures tremendously increased in recent years and will further rise in the near future. In our study we will focus on colonoscopies.
Patients undergoing such interventions expect a safe and in particular comfortable manner of riding out those routines. It is thus not surprising that the demand for sedation during endoscopic procedures by the patient and the endoscopist has increased nowadays.
This trial focuses on patient and gastroenterologist satisfaction and patient safety. The study thereby will be performed comparing three commonly used strategies for sedation: alfentanil * given by endoscopist - will be compared with fentanyl/midazolam based sedation by gastroenterologist and anesthesia nurse accomplished propofol/alfentanil sedation.

Study objective

The aim of the present study is to investigate the differences in patient and endoscopist satisfaction and experiences and patient*s safety with different sedation protocols.

Study design

Study will be performed as a randomized controlled trial.

Intervention

not applicable

Study burden and risks

Measurements which were taken during colonoscopy reflecting common clinical practice. Patients and gastroenterologists have to fill in questionnaires before and after the intervention.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Eligible patients for participation in this clinical trial are those planned to undergo elective diagnostic or therapeutic colonoscopy.
The patients must comply with the following criteria in order to be eligible to participate in this clinical study: Age range * 18 years, ASA classification I * IV. Written informed consent.

Exclusion criteria

Age range < 18 years
ASA classification V
Allergic reaction to planned medication in the patients* medical history
Unregulated hypertension
Bradycardia, arrhythmia

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2010
Enrollment:	180
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Dormicum
Generic name:	Midazolam
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Fentanyl
Generic name:	Fentanyl
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Propofol
Generic name:	Propofol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Rapifen
Generic name:	Alfentanil
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	21-05-2010
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2010-020502-15-NL
CCMO	NL31863.018.10