Effect of Acupuncture on sedation requirement during Colonoscopy (EAcCo)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON39862

Source
ToetsingOnline

Brief title
Acupuncture and sedation requirements

Condition

- Gastrointestinal therapeutic procedures

Synonym
bowel endoscopy, colonoscopie

Research involving
Human

Sponsors and support

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

Intervention

Keyword: acupuncture, colonoscopy, sedation

Outcome measures

Primary outcome

Primary endpoint: Reduction of sedatives for colonoscopies by using additional

acupuncture compared to sedation alone.

Secondary outcome

Secondary endpoints: Patients* satisfaction after colonoscopy by using

additional acupuncture compared to sedation alone.

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 routine procedures. It is thus not surprising that the demand for sedation during endoscopic procedures by the patient and by the endoscopist has increased nowadays. One standard regime (propofol/alfentanil sedation provided by an anaesthesia nurse) is known to provide excellent sedation. However, the combination propofol/alfentanil could be associated with respiratory and cardiovascular depression. Therefore, other methods that induce an adequate level of sedation without respiratory depression or those measures able to decrease the dosage of propofol/alfentanil are of increasing interest to clinicians. Addition of acupuncture could be one possible option.
Acupuncture is a safe procedure without major complications. It is accepted by the WHO for indications such as pain therapy, treatment of anxiety, sleeplessness, and fearful disorders.

Study objective

We hypothesize that acupuncture reduces the dosage of sedatives for colonoscopies. We will compare three groups to test our hypothesis. One group

will receive verum-acupuncture, another group sham-acupuncture and the third group will be the control group. All three groups will receive standard sedation with propofol/alfentanil.
Primary endpoint of the study is the dosage propofol used for colonoscopies in combination with a standard dosage of alfentanil in the verum- and the control group. The third group (sham acupuncture) is necessary to test if there is any placebo effect produced by acupuncture itself, as it is often mentioned and associated in acupuncture treatments in pain therapy.
Secondary endpoint is patient and gastroenterologists satisfaction with the procedure, determined with a questionnaire.

Study design

The study will be performed as an blinded randomized controlled trial.

Intervention

Patients will be studied during the endoscopic procedure, where they will be included in one of three different acupuncture regimes, with verum, sham- and placebo acupuncture. In total every patient will be needled with six needles and treated with electro-acupuncture during the colonoscopy.

Study burden and risks

Measurements that will be made during colonoscopy reflect common clinical practice. Patients have to fill in questionnaires before and after the intervention and have to perform the Trieger test.
Acupuncture is a safe procedure without complications.

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 * III. Written informed consent.

Exclusion criteria

Age range < 18 years, ASA classification IV or higher
Nickel allergy (acupuncture needles), Pacemaker (Application of electroacupuncture)
psychiatric and neurologic disorders, use of anticoagulants

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-02-2014
Enrollment:	153
Type:	Actual

Medical products/devices used

Generic name:	acupuncture needles and electroacupuncture tool
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-05-2013
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
CCMO	NL41966.018.12

Study results

Date completed:	14-02-2017
Actual enrolment:	153