Reduces intravenous lidocaine the need of alfentanyl during colonoscopy under Procedural Sedation and Analgesia?

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The primary objective of this study is to evaluate whether lidocaine reduces the need of alfentanyl during colonoscopy in patients with IBD.The secondary objective of this study is to evaluate whether lidocaine reduces the incidence of respiratory…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44265

Source
ToetsingOnline

Brief title
LiSA

Condition

- Other condition

Synonym
procedural sedation and analgesia

Health condition

procedurele sedatie en analgesie (PSA)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Alfentanyl, Colonoscopy, Lidocaïne, Procedural sedation and analgesia

Outcome measures

Primary outcome

The primary objective of this study is to evaluate whether intravenously

lidocaine reduces the need for alfentanyl during colonoscopy in patients with

IBD

Secondary outcome

Incidence of hypotension (a mean arterial pressure (MAP < 60 mmHg), is

recorded as an adverse event if an intervention is performed to improve the

blood pressure.6

These interventions include administration of:

- IV Fluid

- Medications

Incidence of oxygen desaturation (<92%), is recorded as an adverse event if an

intervention is performed to improve the oxygen saturation7

These interventions include the following:

- Vigorous tactile stimulation

- Airway repositioning

- Suctioning

- Increased oxygen delivery

- Oral or nasal airway placement

- Application of positive pressure or ventilation with bag mask

Incidence of unpleasant recall of the procedure.

Postprocedural NRS

Incidence of PONV

Incidence of adverse effects of lidocaine:

light headedness, tinnitus, dizziness, blurred vision or double vision, metal

taste .

Total propofol dose

Colonoscopy time

Study description

Background summary

Colonoscopy is a commonly performed procedure to diagnose or follow up inflammatory bowel disease (IBD) like Crohn*s disease and ulcerative colitis. However, especially in this patient category, this can be a very uncomfortable and painful procedure.12 Patients with IBD are known for visceral afferent hypersensitivity caused by the chronic, recurrent, inflammatory characteristics and has a significantly higer prevalence of narcotic alalgesic use compared with the general population.13,17

PSA is commonly used during colonoscopy to facilitate the procedure and relieve patient*s discomfort.14
Propofol in combination with a short-acting opioid i.e. alfentanyl is commonly used for PSA.1 This combination during colonoscopy is associated with greater patient satisfaction and less pain when compared with midazolam/fentanyl.4
Yet some serious adverse cardiorespiratory complications related to PSA can occur in up to 20% of the patients, i.e. hypotension, bradycardia, and respiratory depression.15
There is a continuous search to find alternatives, which can minimize the risk for these adverse effects, but with equally quality of PSA.

Study objective

The primary objective of this study is to evaluate whether lidocaine reduces the need of alfentanyl during colonoscopy in patients with IBD.

The secondary objective of this study is to evaluate whether lidocaine reduces the incidence of respiratory depression, hypotension, PONV and postprocedural pain

Study design

single centre double-blinded randomized placebo-controlled trial

Intervention

The intervention group receives lidocaine 1.5 mg/kg in 5 minutes followed by a continuous infusion of 2 mg/kg/hour body weight intravenously. The placebo group will receive saline in equivalent volumes and time

Study burden and risks

All measurement and handlings to the patients which participate in this study are part of standard care.
Patients will have little extra risks due to the known low and non-toxic plasma levels with this commonly used infusing regimen of lidocaine. Monitoring of patients will ensure that any potential side effect or adverse event are noticed and treated as quickly as possible.
The benefit for the patients can be that less alfentanyl needs to be given during colonoscopy, which can lead to less negative side effects like hypotension,
respiratory depression and PONV.

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

patients with IBD, between 18 and 65 years, which are scheduled for a colonoscopy with PSA

Exclusion criteria

Pregnancy.
Emergency colonoscopy.
Known allergies for study medication
Known rhythm disorders i.e. second or third degree AV block
BMI >35
Obstructive sleep apnea syndrome
Pregnancy.
Emergency colonoscopy.
Known allergies for study medication
Known rhythm disorders i.e. second or third degree AV block
BMI >35
Obstructive sleep apnea syndrome

Study design

Design

Study phase:	4
Study type:	Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-11-2016
Enrollment:	76
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Lidocaine
Generic name:	Lidocaine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	28-07-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-09-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-11-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2016-002210-46-NL
CCMO	NL56640.091.16

Study results

Date completed:	27-11-2018
Actual enrolment:	82