ISRCTN47787339 https://doi.org/10.1186/ISRCTN47787339

Does lidocaine act as a painkiller during colonoscopy?

Submission date
06/02/2019

Recruitment status
No longer recruiting

Registration date
25/02/2019

Overall study status
Completed

Last Edited
26/08/2022

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Colonoscopy is a commonly performed procedure to diagnose or follow up an inflammatory bowel disease (IBD) like Crohn's disease and ulcerative colitis. For some of these patients, this can be a very painful procedure. Propofol anaesthetic in combination with a short-acting opioid painkiller i.e. alfentanil is commonly used for procedural sedation and analgesia (PSA). However, alfentanil can induce some serious adverse effects like low blood pressure, slow heart rate, and slow breathing. Administration of lidocaine during an operation has a proven beneficial effect in abdominal surgery, reducing pain after operation the need for strong opiods. We expect that intravenous lidocaine will reduce the need for alfentanil during colonoscopy.

Who can participate?
Any patient who is undergoing a colonoscopy and is willing to participate in a clinical trial.

What does the study involve?
Participants in the intervention group will receive lidocaine during the normal procedure of colonoscopy. Patients who are included in the placebo group of the study will receive placebo.

What are the possible benefits and risks of participating?
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.

Where is the study run from?
Radboud Universitair Medisch Centrum, Geert Grooteplein Zuid 10, Nijmegen, 625 GA, Netherlands

When is the study starting and how long is it expected to run for?
The study will run from November 2016 to November 2018.

Who is funding the study?
Radboud Universitair Medisch Centrum, Netherlands.

Who is the main contact?
Mr. Twan Aalbers, twan.aalbers@radboudumc.nl

Contact information

Type(s)
Public

Contact name
Mr Twan Aalbers

Contact details
Radboud Universitair Medisch Centrum
Geert Grooteplein Zuid 10
huispost 717
Nijmegen
Netherlands
6525 GA
+31243614406
twan.aalbers@radboudumc.nl

Additional identifiers

Clinical Trials Information System (CTIS)
2016-002210-46

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NL56640.091.16

Study information

Scientific Title
Does intravenous lidocaine reduce the need for alfentanil during colonoscopy under procedural sedation and analgesia?

Acronym
LiSA

Study objectives
We hypothesize that intravenous lidocaine reduces the need for alfentanil during colonoscopy

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/09/2019, Human Research Committee region Arnhem-Nijmegen (p/a Radboudumc, house post 628, P.O. box 9101, 6500 HB Nijmegen, The Netherlands; +31 24 361 3154; commissiemensgebondenonderzoek@radboudumc.nl), ref: 2016-2624

Study design
Single centre double-blinded randomized placebo-controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Healthcare domain: procedural sedation and analgesia (PSA)

Interventions
intervention: At the start of PSA, patient will receive 1.5 mg/kg intravenous bolus, followed by a continuous infusion of 2 mg/kg/h lidocaine during the colonoscopy.
Patients who are included in the placebo group of the study will receive saline in equivalent volumes and time.
At the end of the colonoscopy subjects will be monitored until they reach an Aldrete recovery score of nine or higher and for at least 30 minutes according to the local PSA protocol. Afterward, patients will be discharged. A letter with instructions is sent to the general practitioner.
All adverse events reported spontaneously by the subject of observed by the investigator or his staff will be recorded. Serious adverse events have been reported to the accredited local ethics committee.
76 patients are randomized to either intravenous lidocaine treatment or placebo by the research unit of the anesthesiology department.
The subjects were randomized into groups that resulted in equal sample sizes. There were two treatment groups (treatment medication (A) versus placebo (B)). Treatment A and B were written on pieces of paper, equal amounts of A and B. The pieces of paper were put into an envelope and blindly selected one at a time. The first paper drawn was assigned to the first patient, the second was assigned to the second subject and so on. Two research coordinators were present during this randomization process.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Lidocaïne 1%

Primary outcome(s)
Alfentanyl dose (mcg) required to maintain a score < 4 on the Facial Pain Rating Scale (Wong baker face scale) during the procedure.

Key secondary outcome(s))
1. Total propofol dose (mcg) required to maintain sedation level 4-5 on The Ramsey Sedation Scale during the procedure.
2. Infusion time measured in minutes from delivery to end of sedation.
3. Incidence of oxygen desaturation (defined as < 92%) measured continuously during the procedure.
4. Incidence of hypotension (defined as mean arterial pressure < 60 mmHg) measured every 5 minutes during the procedure.
5. Pain score measured using the numerical rating scale after the procedure.
6. Incidence of postprocedural nausea and vomiting measured by patient interview after the procedure.
7. Incidence of adverse effects of lidocaine (e.g. tinnitus, blurred vision or double vision, metal taste during procedure) measured by patient interview after the procedure.

Completion date
27/11/2018

Eligibility

Key inclusion criteria
1. Colonoscopy performed under PSA
2. Age 18-65 years
3. Inflammatory bowel disease: Crohn’s disease or ulcerative colitis
4. Informed consent
5. ASA classification 1 or 2

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
76

Key exclusion criteria
1. Pregnancy
2. Emergency colonoscopy

3. Allergies for study medication
4. Rhythm disorders i.e. first, second or third degree AV block
5. Brugada syndrome
6. Cardiomyopathy
7. BMI >35
8. BMI <18
9. Obstructive sleep apnea syndrome
10. Uncontrolled hypertension

Date of first enrolment
24/11/2016

Date of final enrolment
13/11/2018

Locations

Countries of recruitment
Netherlands

Study participating centre
Radboud Universitair Medisch Centrum
Geert Grooteplein Zuid 10
Nijmegen
Netherlands
6525 GA

Sponsor information

Organisation
Radboud Universitair Medisch Centrum

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Radboud Universitair Medisch Centrum

Alternative Name(s)
Radboudumc, Radboud University Medical Center, Radboud University Nijmegen Medical Center, RUNMC

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and the current study will be available upon request from Twan Aalbers (twan.aalbers@radboudumc.nl). Type of data: SPS datasheet. Data will become available after publication and is available until January 2034. Data will be shared in the context of scientific research. No informed consent has been given from participants. Only anonymous data is available.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/07/2020	22/08/2022	Yes	No
Basic results		18/11/2019	29/11/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 4	01/10/2016	26/08/2022	No	No