ISRCTN63417725 https://doi.org/10.1186/ISRCTN63417725

Lidocaine in major abdominal surgery: a pilot study to better understand its effects on inflammation and small vessels

Submission date
07/06/2020

Recruitment status
No longer recruiting

Registration date
15/06/2020

Overall study status
Completed

Last Edited
25/06/2020

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims.
Abdominal surgery includes any operation on organs including the stomach, gallbladder, small or large intestine, liver, pancreas, spleen and appendix. Major abdominal surgery is associated with inflammation and damage of the inside layer of blood vessels (called the endothelial glycocalyx). The anti-inflammatory effects of lidocaine, a commonly used local anesthetic, were recently associated with protection of this thin layer. The aim of this study is to find out whether lidocaine can prevent endothelial dysfunction after major abdominal surgery.

Who can participate?
Patients aged 18 or over who are scheduled for major abdominal surgery.

What does the study involve?
Patients are randomly allocated to receive either lidocaine or placebo (dummy drug) during their surgery. Participants undergo three sessions of harmless measurements (before, 1-3 hours and 24 hours after surgery), performed with an ultrasound machine on the right arm and a small electrode on the right hand. A pneumatic cuff will be used to stop blood circulation in the hand for 5 minutes. Three blood tests are associated with these measurements, but they are performed during regular testing before and after surgery without any extra needle insertions.

What are the possible benefits and risks of participating?
Benefits are the presumed reduction in inflammation and thus preservation of the endothelial glycocalyx; and a highly controlled anesthesia protocol with optimization of fluid perfusion and pain reduction. Risks connected to the use of the study drug occur at extremely low frequency at doses used in this study. These are dizziness, metallic taste and a slight reduction in arterial blood pressure.

Where is the study run from?
Erasmus Hospital (Belgium)

When is the study starting and how long is it expected to run for?
December 2016 to March 2017

Who is funding the study?
Erasmus Hospital (Belgium)

Who is the main contact?
Dr Marco Pustetto
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2016-003918-27

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
LICAM:2016-003918-27

Study information

Scientific Title
Intravenous lidocaine to prevent endothelial dysfunction after major abdominal surgery: a randomized controlled pilot trial

Acronym
LICAM17

Study objectives
1. To demonstrate the effects of lidocaine on endothelial glycocalyx flaking in major abdominal surgery
2. To confirm that major abdominal surgery leads to a partial disruption of the endothelial glycocalyx
3. To demonstrate that it is also associated with an alteration of flow-mediated dilation of the brachial artery and of StO_2 of the thenar eminence, measured by NIRS, after a vascular occlusion test
4. To demonstrate that these alterations are related to the level of glycocalyx disruption measured by Syndecan-1
5. To demonstrate that the protection of endothelial glycocalyx leads to a reduction in fluids administered in the peri-operative period following a goal-directed protocol

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/10/2016, Erasmus Hospital Ethics Committee (808 route de Lennik, B-1070 Brussels, Belgium; +32 (0)2 555 3707; comite.ethique@erasme.ulb.ac.be), ref: P2016/404/2016-003918-27

Study design
Interventional single-center randomized double-blinded controlled pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Patients admitted to be operated for major abdominal surgery, i.e. duodeno-cephalo-pancreasectomy, total mesorectal excision, total and partial nephrectomy, total and partial gastrectomy, debulking for ovarian tumeur, total cystectomy.

Interventions

Participants were randomly assigned to one of two groups in a 1:1 ratio, based on Efron's biased coin randomisation procedure generated with NCSS v10 Statistical Software (2015, NCSS, Llc. Kaysville, UT, USA).

Patients allocated to the intervention group receive 1.5 mg kg-1 (total body weight [TBW]) of 1% lidocaine just before anesthesia induction, which is immediately followed by a 2 mg kg-1 h-1 (TBW) continuous intravenous infusion until skin closure. Patients allocated to the placebo group receive an equivalent volume of 0.9% saline (0.15 ml kg-1 bolus and 0.2 ml kg-1 h-1 continuous intravenous infusion). Anesthesia protocol is standardized in both groups. Hemodynamics are managed with a goal-directed therapy protocol, based on stroke volume variation and mean arterial pressure.

Duration of intervention: from anesthesia induction until skin closure. Duration of follow-up: 24 hours after surgery.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Lidocaine

Primary outcome measure
Syndecan-1 concentration measured by classic sandwich enzyme-linked immunosorbent assay at baseline (before surgery), 1-3 h post surgery and 24 h

Secondary outcome measures
1. StO_2-baseline, StO_2-ischemic slope and StO_2-reperfusion slope measured using near-infrared spectroscopy on thenar eminence, before during and after a vascular occlusion test, at baseline (before surgery), 1-3 h post surgery and 24 h
2. Brachial artery baseline diameter, maximal flow-mediated dilation and area under the curve of estimated shear rate of hyperaemic flow measured by ultrasonography of the brachial artery coupled with an automated edge detection software, before during and after a vascular occlusion test, at baseline (before surgery), 1-3 h post surgery and 24 h

Overall study start date
01/07/2016

Completion date
30/04/2017

Eligibility

Key inclusion criteria
1. Over 18 years old
2. Planned major abdominal surgery: duodeno-cephalo-pancreasectomy, total mesorectal excision, total and partial nephrectomy, total and partial gastrectomy, debulking for ovarian tumour, total cystectomy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
40

Key exclusion criteria
1. Urgent surgery
2. Severe heart conduction block without implantable pacemaker
3. Severe liver and kidney insufficiency
4. Major liver resection
5. Acute heart failure
6. Allergic reaction to lidocaine or other amide-linked local anesthetics

Date of first enrolment
01/12/2016

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
Belgium

Study participating centre
Hôpital Erasme
808, route de Lennik
Bruxelles
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1070

Sponsor information

Organisation
Erasmus Hospital

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Sponsor type
Hospital/treatment centre

Website
https://www.erasme.ulb.ac.be/fr

ROR
https://ror.org/05j1gs298

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Erasmus Hospital

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/08/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analyzed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	23/06/2020	25/06/2020	Yes	No