

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

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>07/06/2020   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>15/06/2020 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>25/06/2020       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> 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

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
2016-003918-27

**Protocol serial number**  
LICAM:

## 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<sub>2</sub> 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

### **Primary study design**

Interventional

### **Study design**

Interventional single-center randomized double-blinded controlled pilot trial

### **Study type(s)**

Treatment

### **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<sup>-1</sup> (total body weight [TBW]) of 1% lidocaine just before anesthesia induction, which is immediately followed by a 2 mg kg<sup>-1</sup> h<sup>-1</sup> (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<sup>-1</sup> bolus and 0.2 ml kg<sup>-1</sup> h<sup>-1</sup> 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(s)**

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

**Key secondary outcome(s)**

1. StO<sub>2</sub>-baseline, StO<sub>2</sub>-ischemic slope and StO<sub>2</sub>-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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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

Belgium

1070

**Sponsor information****Organisation**

Erasmus Hospital

**ROR**

<https://ror.org/05j1gs298>

**Funder(s)****Funder type**

Hospital/treatment centre

**Funder Name**

Erasmus Hospital

# Results and Publications

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> | results | 23/06/2020   | 25/06/2020 | Yes            | No              |