Postoperative sublingual microvascular blood flow following esophagectomy and the effect of dobutamine

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- Primary Objective: to investigate whether the administration of a small amount of dobutamine postoperatively is able to positively influence the sublingual microcirculation in patients who are undergoing esophagectomy.- Secondary Objective: to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal vascular conditions
Study type	Interventional

Summary

ID

NL-OMON35417

Source
ToetsingOnline

Brief title
Sublingual microcirculatory alterations in esophagectomy patients

Condition

- Gastrointestinal vascular conditions

Synonym
esophagectomy, Sublingual microvascular blood flow

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - Dobutamine, - Esophagectomy, - Microvascular blood flow

Outcome measures

Primary outcome

The aim of our study is to observe the postoperative sublingual microvascular perfusion changes in functional capillary density (FCD), perfused vessel density (PVD) and microvascular flow index (MFI), in patients undergoing esophagectomy and the effect of dobutamine intravenously.

Secondary outcome

To observe the effect of low dose dobutamine on heart rate and cardiac output.

Study description

Background summary

Typical complications of esophagectomy and gastric tube reconstruction include leakage and stenosis from the anastomosis of the neck, which may be due to the compromises microvascular blood flow (MBF). Recently Jhanji et al. showed that MBF can be of predictive value for the postoperative course: those with a disturbed postoperative microvascular perfusion have more postoperative complications. In another study a similar predictive phenomenon was seen in patients with septic shock. The patients who ultimately died from the shock, had a worse microcirculation in the first 24 hours, than those who survived the shock. Administration of dobutamine in these patients improved the microvascular perfusion, independent of global hemodynamic parameters. It is therefore important to investigate how the postoperative microcirculation behaves in patients undergoing esophagectomy with gastric tube reconstruction, and if this can positively be influenced by giving a low dose dobutamine.

Study objective

- Primary Objective: to investigate whether the administration of a small amount of dobutamine postoperatively is able to positively influence the sublingual microcirculation in patients who are undergoing esophagectomy.

- Secondary Objective: to observe what effect postoperative administration of dobutamine has on cardiac output, postoperative morbidity, IC- and hospital stay

Study design

This study is designed as a prospective double blind randomized controlled trial.

Intervention

Patients who are undergoing an esophagectomy with gastric tube reconstrucion are randomised in 2 groups; patients with and without intravenous administration of low dose dobutamine during the first 2 postoperative days.

Study burden and risks

The microvascular perfusion is observed in all patients by placing a small handheld camera, SDF-camera gently under the tongue. This Sidestream Dark Field (SDF) imager is a new and more improved method to observe the subliungual microcirculation at bedside, see page 12 of the protocol for more explanation. The observation is not painful or invasive. By placing the camera at the mucosa under the tongue a good image can be made of the microvascular perfusion. This measurement takes place once a day for a total of 4 days. Each measurement approximately takes 25-30 min. Patients who are classified in the intervention group will immediately be connected to a postoperative intravenous dobutamine pump. This will remain connected to 2 days postoperatively. This represents no additional burden for the patient because the patient won*t notice anything due to the anesthesia of the. No additional lines have to be punctured.

A side effect of dobutamine is that it can cause tachycardia. The chance of this is however very small, because the dose used in this study is at most half of the normally effective dose used in the IC. In addition, the administration can immediately be stopped with a half life time of 2 min. In previous studies with dobutamine good results are seen in the sublingual microvascular perfusion. Therefore we expect a good improvement of the microvascular perfusion.

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

- Age range: > 18 years
- ASA classification I - III
- Written informed consent
- Elective esophagectomy

Exclusion criteria

- Age range: < 18 years
- ASA classification IV and V
- Diabetes Mellitus (bad microvessels)
- Administration of drugs with positive inotropic effects
- Patients with previous cardiac events (previous cardiac arrests and arrythmia)
- Informed written consent missing

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-05-2010
Enrollment:	20
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	23-04-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	27-04-2010
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 26013
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2009-015949-23-NL
CCMO	NL29699.078.09
OMON	NL-OMON26013