# Microvascular blood flow under the tongue after esophagectomy surgery and the effect of dobutamine.

No registrations found.

| Ethical review        | Not applicable |
|-----------------------|----------------|
| Status                | Recruiting     |
| Health condition type | -              |
| Study type            | Interventional |

# **Summary**

## ID

NL-OMON26013

Source NTR

**Brief title** Sublingual microcirculatory alterations in patients undergoing esophagectomy (SMAIPUE)

#### Health condition

- Esophagectomy patients / Buismaagpatienten
- Microvascular Blood Flow / Microcirculatie
- SDF (Sidestream Dark Field) imaging / SDF meting

## **Sponsors and support**

**Primary sponsor:** University Medical Center **Source(s) of monetary or material Support:** self-financing research: Intensive Care Erasmus MC

## Intervention

#### **Outcome measures**

#### **Primary outcome**

The aim of our study is to observe 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**

Background of the study:

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.

#### Objective of the study:

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.

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Study population:

Patients who are suffering from esophageal cancer and are undergoing elective transthoracic or transhiatal esophagectomy with gastric tube reconstruction.

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 objective**

We have stated the hypothesis that a reduction in sublingual microvascular perfusion following esophagectomy is not only a symptom of a generalized inflammatory stress response but can also be predictive for the development of postoperative complications. We expect that postoperative administration of dobutamine can reduce the impairment of microvascular perfusion as well as the incidence of postoperative complications, with finally sooner discharge from the ward.

#### Study design

Sublingual microvascular blood flow will be measured once a day for a total of 4 days, one day pre-, directly after surgery (before and after start of study medication) and 2 days postoperatively.

#### Intervention

The intervention group will receive low dose dobutamine (max. of  $2.5 \ \mu g/kg \cdot min$ ) during surgery or directly postoperative, whereas the control group will receive a similar volume of saline.

# Contacts

#### Public

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# **Eligibility criteria**

## **Inclusion criteria**

- 1. Age range: > 18 years;
- 2. ASA classification I III;
- 3. Written informed consent;
- 4. Elective esophagectomy.

All inclusion criteria must be met; otherwise the patient cannot be enrolled in the study.

# **Exclusion criteria**

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

# Study design

# Design

Study type:

Interventional

| Intervention model: | Parallel                      |
|---------------------|-------------------------------|
| Allocation:         | Randomized controlled trial   |
| Masking:            | Double blinded (masking used) |
| Control:            | Placebo                       |

## Recruitment

| NL                        |             |
|---------------------------|-------------|
| Recruitment status:       | Recruiting  |
| Start date (anticipated): | 01-03-2010  |
| Enrollment:               | 30          |
| Туре:                     | Anticipated |

# **Ethics review**

| Not applicable    |        |
|-------------------|--------|
| Application type: | Not ap |

Not applicable

# **Study registrations**

# Followed up by the following (possibly more current) registration

ID: 35417 Bron: ToetsingOnline Titel:

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

No registrations found.

## In other registers

| ID                                  |
|-------------------------------------|
| NL2155                              |
| NTR2279                             |
| NL29699.078.09                      |
| ISRCTN wordt niet meer aangevraagd. |
| NL-OMON35417                        |
|                                     |

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# **Study results**

## Summary results

N/A