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

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Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26013

Bron
NTR

Verkorte titel
Sublingual microcirculatory alterations in patients undergoing esophagectomy (SMAIPUE)

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center
Overige ondersteuning: self-financing research: Intensive Care Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2010
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35417
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2155
NTR-old	NTR2279
CCMO	NL29699.078.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35417

Resultaten

Samenvatting resultaten
N/A