Real-time Quantitative Optical Perfusion Imaging in Surgery: A Prospective, Observational, In-vivo, Human, Single-Center Study.

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Primary objective- To assess the reliability and explore the validity of Fluorescence Imaging, Laser Speckle Contrast Imaging, Optical Coherence Tomography and Sidestream Dark Field as a perfusion imaging modality, during free flap reconstruction...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON43865

Source
ToetsingOnline

Brief title
Optical Perfusion Imaging in Surgery.

Condition

- Soft tissue therapeutic procedures

Synonym
poor blood perfusion during Surgery, Vascular Compromise

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Avantes,Quest Medical Imaging,ZonMw

Intervention

Keyword: Optical Imaging, Perfusion, Surgery

Outcome measures

Primary outcome

To assess the reliability of the techniques we will focus on the interobserver agreements. We will score the images on the following 5 specific hemodynamic parameters, tailored to the specific characteristics of the devices. To explore the validity of the techniques we will compare the differences in images of good versus sparse blood flow in terms of the same parameter.

Secondary outcome

To technical compare the four imaging modalities in terms of resolution, imaging depth and field of view.

Study description

Background summary

Surgeons are nowadays unable to visualize and quantitatively evaluate microvascularisation in real-time during surgery. Complications due to vascular compromise are a major problem, especially in reconstructive surgery. Poor blood perfusion leads to ischemia and even tissue necrosis because of the lack of nutrients.

In patients with esophageal cancer who receive an esophagectomy can undergo a reconstruction forming a 'tube' of gastric tissue. Ischemia of this 'gastric-tube' occurs in 5-20% of patients, which results in anastomotic leakage and stenosis, with high morbidity and even mortality. Patients need a re-operation or intensive care unit stay and this is correlated with high costs in healtcare.

In patients with considerable defects due to trauma or disease, e.g. radical

cancer surgery, free flap reconstruction leads to enhanced tissue function and shape repair. Sufficient perfusion of tissue is essential in free-flap transfer success. Despite research, 5% of free flap reconstructions lead to necrosis and tissue loss with a high morbidity and high costs for healthcare.

However, if perfusion and ischemia could be monitored during surgery, then surgeons could change their reconstructive design and the anesthesiologists could improve perfusion with fluids, inotropes or vasopressors, if necessary.

In recent decades, innovative optical techniques have been developed that use the interaction of (harmless) light with tissue. Previous research suggest a powerful role for these techniques in medical diagnostics. Optical Coherence tomography (OCT), Indocyanine Green (ICG) fluorescence, Sidestream Darkfield Microscopy sDF) and Laser Speckle Imaging (LSI) could all be valuable in imaging perfusion during surgery.

Study objective

Primary objective
- To assess the reliability and explore the validity of Fluorescence Imaging, Laser Speckle Contrast Imaging, Optical Coherence Tomography and Sidestream Dark Field as a perfusion imaging modality, during free flap reconstruction and gastric tube reconstruction.
To assess the reliability of the techniques we will focus on the interobserver agreement. We will score the images on the following 5 specific hemodynamic parameters (following the criteria of perfusion interpretation stated by de Backer et al.1): total vessel density, proportion of perfused vessels, vessel diameter, RBC concentration, and blood flow velocity.To explore the validity of the techniques we will compare the differences in images of good versus sparse blood flow in terms of the above defined 5 quantitative parameters.

Secondary objectives
- To technical compare the four imaging modalities in terms of resolution, imaging depth and field of view.

Study design

This is a single-center, prospective, observational, in-vivo phase II pilot study of 40 evaluable adult patients receiving reconstructive surgery in terms of free flap surgery (n=20) and gastric-tube surgery (n=20). Total study duration is 2 years. During reconstructive surgery, images of tissue perfusion will be made with the four optical techniques at different time periods.

Study burden and risks

All techniques use harmless light to image perfusion during surgery. Patients

are already planned for this type of surgery, so this extra procedure of imaging carries no additional risk to the patient. In each patient all the techniques will image before and after reconstruction of tissue (free flap surgery) or before and after ephedrine (in gastric tube surgery). The only risk will be the additional time of imaging during surgery, which added about 10-20 minutes to the overall surgical procedure. Furthermore, we will use indocyanine green for Fluorescence Imaging and ephedrine as perfusion improving agent, which are both FDA approved. Only patients with contraindications could be at risk, so these patients will be excluded from our study (see exclusion criteria).
We therefore classify the proposed research as a study with negligible risk according to the NFU- (Nederlandse Federatie van Universitaire Medische Centra) criteria for human research.

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 * 18 years
- Scheduled for reconstructive surgery with free flap reconstruction or laparoscopic transhiatal and 3-stage transthoracic gastric tube surgery.

Exclusion criteria

Both free flap surgery as gastric tube surgery:
- Allergic to iodide (indocyanine green)
- Hyper-thyroidism
- Breastfeeding
- No informed consent;In case of gastric tube surgery, and the use of ephedrine:
- Allergic to ephedrine
- Ischeamic heart disease
- Thyrotoxicosis
- Autonomic thyroid adenomas
- Intraoperative hypertension or tachycardia

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2015
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Fluorescence Imaging;Laser Speckle Imaging;Optical

	Coherence Tomography;Sidestream Darkfield Microsc
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-06-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-04-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-10-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL52377.018.15