Determining critical thresholds of tissue perfusion using indocyanine green in reconstructive surgery

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON54423

Source
ToetsingOnline

Brief title
ICG in reconstructive surgery

Condition

- Other condition
- Skin and subcutaneous tissue therapeutic procedures

Synonym
Flap surgery, tissue reconstruction

Health condition

weke delen en bot therapeutische verrichtingen

Research involving
Human

Sponsors and support

Primary sponsor: Plastische chirurgie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fluoresence, Indocyanine green, Reconstructive surgery, Tissue perfusion

Outcome measures

Primary outcome

Objective perfusion parameters include:

1. Maximum perfusion intensity (Imax, units) in a normal vascularized reference

frame

2. Maximum perfusion intensity (Imax, units) in region of interest

3. Relative Perfusion (RP,%, = 1/2)

Secondary outcome

1. Lap Failure: Quantified as I <5%; II 5-15%, III 15-50%, IV> 50%, V complete

2. Wound infection defined as none, local wound treatment, antibiotics, or

hospitalization.

3. Skin necrosis defined as none, partial thickness, and full thickness.

4. Delayed union after 6 months or non-union after 12 months

Study description

Background summary

The success or failure of a reconstruction is largely related to the vascularization of the operated area. Especially in the presence of non-vascularized material such as an implant or osteosynthesis material or a need for adjuvant radiotherapy, adequate perfusion is of crucial importance. Various techniques are used in reconstructive surgery to deliver

well-vascularized tissue, including local transpositions, pedicled skin / bone / muscle flaps or a so-called free flap, in which a tissue flap based on a donor vessel is detached and anastomosed elsewhere on an acceptor vessel. Nowadays we mainly focus on clinical signs such as capillary refill, temperature, color and bleeding of the wound edges to access the vitality of tissue. Alternatives include optical coherence imaging, laser Doppler, saturation measurements and infrared thermography. A previous review in our institute showed that the Doppler or fluorescence research has the most potential to quantify perfusion. A doppler measurement (invasive or not) provides local information about the patency of a vessel or anastomosis, but this does not provide information about the exact blood flow in the different regions in an operating area.
Near infrared fluorescence (also near infrared fluorescence angiography, NIR FA) with ICG administration is an innovative technique to quantify tissue perfusion. ICG was introduced by Fox et al. in 1957. and is widely implemented in the medical field today. ICG is used for diagnostic purposes only. It has been used successfully in vascular surgery, oncologic surgery and colorectal surgery. Use of ICG to measure bone perfusion has been used less often, but has been published in animal and cadaver models and even in patients. Based on the results obtained in other subspecialties, NIR fluorescence appears to be a promising way to quantify tissue perfusion in reconstructive surgery.

Study objective

Our primary objective is to determine critical values of tissue perfusion for reconstructive surgery be quantification using near-infrared fluorescence. The fluorescence signal will be derived from a signal to noise ratio. The primary outcome measures include the maximum and relative perfusion intensity.

The ultimate clinical goal is to prevent complications including partial lap failure, wound dehiscence, wound infections and osseous non - union and these parameters are being collected as secondary objectives.

Study design

This is an umbrella protocol that can be used for several prospective cohorts with a similar study design. The cohorts will be included at the Amsterdam UMC, location AMC and VUMC. We will include patients undergoing surgical debridement (1) after trauma or radionecrosis and / or reconstructive surgery (2). As soon as the patient is scheduled for surgery, we will provide the patient information by mail. Our goal is to inform the patients at least one week in advance and bring it to the attention again upon admission. There will rarely be a patient who cannot give informed consent prior to the planned operation because of major trauma in which the patient is operated immediately.

Study burden and risks

It's a very minor effort for the patient and the only risk lies in an allergic response for which the risk is very low.

Contacts

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patient undergoing pedicled or free flap surgery which may be or may not be proceeded by debridement of affected tissue.

Exclusion criteria

Allergy Iodine
Allergy shellfish

Pregnancy or breastfeeding
Epilepsy
Kidney failure with eGFR <60

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-06-2023
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	17-05-2023
Application type:	First submission
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	NL74852.029.21