Indocyanine Green for Perfusion Assessment of DIEP Flaps: A Dutch Multicenter Randomized Controlled Trial

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To determine whether fluorescence imaging using ICG for the assessment of DIEP flap perfusion during surgery decreases the occurrence of fat necrosis compared to standard intraoperative clinical assessment of DIEP flap perfusion.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON54522

Source
ToetsingOnline

Brief title
DIEP RCT

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
blood flow of skin flaps, flap perfusion

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: niet; onderzoekers worden niet betaald

Intervention

Keyword: DIEP flap, fluorescence, indocyanine green, perfusion

Outcome measures

Primary outcome

Percentage clinically relevant fat necrosis, defined as a palpable mass, either painful or not, and with or without aesthetic complaints, and developed within three months after surgery.

Secondary outcome

• Registration of re-interventions necessary to treat fat necrosis, in numbers and percentages

• Registration of postoperative complications, in numbers and percentages

• Duration of surgery in minutes

• Percentage extra resected tissue of initial flap in grams based on perfusion assessment

• Personal experience/opinion of surgeon performing surgery with fluorescent imaging using ICG. This is graded using the NASA TASK questionnaire.

• Patient satisfaction using BREAST-Q questionnaire

Study description

Background summary

Autologous breast reconstruction after mastectomy due to cancer or prophylactically due to genetically increased risk is frequently performed. A complication that may occur after a deep inferior epigastric artery (DIEP) reconstruction is the occurrence of fat necrosis in the transplanted flap due to ischemia (reperfusion injury). Identification of deep inferior epigastric artery perforators and identification of demarcated ischemic zones of the DIEP

flap can be optimized by using fluorescence imaging with indocyanine green (ICG), as has been demonstrated in previous studies. This could result in less fat necrosis, less partial flap loss, and other complications. A randomized controlled trial would be the best study design to assess the value of ICG in determining the perfusion of DIEP flaps, thereby reducing the occurrence of fat necrosis and other complications.

Study objective

To determine whether fluorescence imaging using ICG for the assessment of DIEP flap perfusion during surgery decreases the occurrence of fat necrosis compared to standard intraoperative clinical assessment of DIEP flap perfusion.

Study design

This is a two-armed randomized controlled trial:
- interventional arm: evaluation of flap perfusion based on 1) clinical parameters, and 2) fluorescence imaging using ICG
- conventional arm: evaluation of flap perfusion based on clinical parameters only

Study burden and risks

The surgery of the patients included in the invervention arm will be extended with approximately 20 minutes to perform NIRF imaging with ICG.
Patients may not be included in case they have an allergy for ICG or Iodine, or schellfish because an allergic reaction might occur. This is described in the literature in <1:40000 patients, and in case an allergy happens this will be a sensitivity reaction of the skin.
The risk will be negligible.
Furthermore, patients will have to take a BREAST-Q questionnaire, this will cost them max 10 minutes.

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

1. Female patients 18 years of age and older
2. Who underwent a mastectomy for breast cancer or prophylactic due to genetic predisposition
3. Patients scheduled for elective surgery for autologous breast reconstruction, uni- or bilateral, using DIEP or msTRAM flaps
4. Written informed consent

Exclusion criteria

1. Allergy to ICG, iodine or shellfish
2. Any medical condition that in the opinion of the investigators could potentially jeopardize the safety of the patient
3. Impaired renal function defined as eGFR< 50 mL/min/1.73m2
4. Adjuvant systemic chemo- and/or local radiotherapy in the 3 months after the DIEP-procedure.

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-04-2022
Enrollment:	280
Type:	Actual

Ethics review

Approved WMO

Date:	15-07-2019
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	13-03-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	29-12-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT05507710
CCMO	NL68623.058.18