Advanced planning of DIEP flap patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29436

Source
Nationaal Trial Register

Health condition

Borstreconstructie breastreconstruction DIEP flap

Sponsors and support

Primary sponsor: Radboudumc Nijmegen
Source(s) of monetary or material Support: Radboudumc Nijmegen

Intervention

Outcome measures

Primary outcome

Number of preoperatively identified perforators found intraoperatively (true positive) in each flap

Time elapsed on dissecting the free skin flap

Secondary outcome

Number of preoperatively identified perforators not found intraoperatively (false positive) in each flap

Number of preoperatively unidentified perforators found intraoperatively (false negative) in each flap

Number of correctly predicted perforators used in transplantation

Total time spent on performing the actual surgery (snijtijd)

Number of postoperative complications

Number of intraoperative complications

NASA TLX score to determine surgeon stress during procedure

Study description

Background summary

Rationale: In a Deep Inferior Epigastric Perforator (DIEP) flap breast reconstruction, a large part of the abdominal fat and skin below the navel is used to form a new breast. The flap relies on blood supply provided by perforators, which are very small in diameter and difficult to detect during the procedure. If a perforator is accidentally severed, the procedure becomes compromised. Prior to surgery a CT scan is made and a handheld Doppler US device is used to indicate the perforator locations on the patients abdomen. This method does not distinguish main axial vessels from perforator arteries at the height of the fascia, cannot assess the deep inferior arteries branching patterns and has a limited penetration depth although essential for obese patients. To overcome this problem we developed an innovative method that consist of a projection system, capable of projecting anatomical data onto the patient. Using the already acquired CT data for vascular assessment, a virtual navigational map for the procedure is created. This map containing the perforator locations, intramuscular trajectory and optionally other anatomical features is projected onto the patient prior to surgery and traced with a marker pen.

We expect shorter preoperative examination times and more intraoperatively relevant information for the surgeon. To investigate this, the harvesting time of the flap and total surgery time will be recorded. Intraoperative complications such as perforator destruction and post-operative complications will be noted. In literature, high surgeon stress has been reported. In this study we also assess the surgeons' task load through a verified checklist developed by NASA named Task Load Index (TLX).

Objective:

Primary Objectives:

Investigate whether the usage of pre-operative projections prior to a deep inferior epigastric

perforator flap breast reconstruction leads to more correctly identified perforator locations and less operation time spend on dissecting the free skin flap compared to the currently used planning method.

Secondary Objectives:

To investigate whether preoperative planning can accurately predict perforators used intraoperatively. To assess the impact of the different planning techniques on the task load of performing the surgery. To evaluate morbidity including fat necrosis, partial or total flap loss, arterial thrombosis, venous congestion and perforator destruction between both groups. To gain insight into the total procedure time.

Study design: Randomized controlled trial, open label
Study population: Age 18 years of older. Patients scheduled for direct, delayed, unilateral or bilateral deep inferior epigastric perforator flap breast reconstruction surgery. Patients willing to participate (written informed consent).
Intervention (if applicable): The control group receives standard care; perforator location planning through US Doppler. The projection group receives additional planning based on CT data and the perforator locations are displayed on the abdomen

Main study parameters/endpoints:

The proportion of correctly and incorrectly identified perforators found with both techniques, compared to intraoperative results in each harvested flap (true positives). The total harvest time for each flap.

Countries of recruitment: Netherlands

Study objective

Investigate whether the usage of pre-operative projections prior to a deep inferior epigastric perforator flap breast reconstruction leads to more correctly identified perforator locations and less operation time spend on dissecting the free skin flap compared to the currently used planning method.

Study design

Pre, intra- and postoperative

Intervention

Localizing perforator locations through handheld Doppler US
or

Localizing perforator locations using a projection based on CTA

Contacts

Public
Radboud UMC
S Hummelink
Nijmegen
The Netherlands
Scientific
Radboud UMC
S Hummelink
Nijmegen
The Netherlands

Eligibility criteria

Inclusion criteria

Age 18 years of older.

Patients scheduled for direct, delayed, unilateral or bilateral deep inferior epigastric perforator flap breast reconstruction surgery.

Patients willing to participate (written informed consent).

Exclusion criteria

Patients with intolerance / hypersensitivity to contrast agent Iomeron (iomeprol)

Patients with inadequate kidney function (due to contrast agent)

Patients who undergo a deep inferior epigastric perforator flap with additional lymph node transfer.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-11-2015
Enrollment:	78
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-07-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42586
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5807
NTR-old	NTR5962
CCMO	NL52994.091.15
OMON	NL-OMON42586

Study results