The influence of dobutamine on the microcirculation in the DIEP-flap

No registrations found.

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

Summary

ID

NL-OMON26226

Source
Nationaal Trial Register

Health condition

Dobutamine, microcirculation, DIEP-flap, Laser Doppler

Sponsors and support

Primary sponsor: Orbis Medisch centrum
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

increase in blood flow (PU, measured by means of laser doppler)

Secondary outcome

- flap necrosis

- fat necrosis

- amount of escape medication used

- quality of life

Study description

Background summary

Since dobutamine in low doses exerts both a vasodilatory as an inotropic effect, infusion during free flap surgery is suggested to increase the arterial flow and hence decrease the complication rate. With this trial we want to investigate whether dobutamine infusion increases the flow in free flap surgery, and consequently decreases the complication rate in a double-blind placebo controlled intervention study.

Study objective

Does intravenous infusion of low doses dobutamine solely peroperative or for 18 more hours postoperative in women undergoing a breast reconstruction by menas of a DIEP flap, increase the blood flow in arterioles after dobutamine infusion as compared to placebo (NaCl 0.9% infusion) measured by means of laser doppler

Study design

- baseline

- peroperative

- postoperative (first day, 2 weeks, 6 weeks and 3 months)

Intervention

- dobutamine peroperative, 18 hours post-operative placebo

- dobutamine peroperative and 18 hours post-operative

- placebo both per- and postoperative

Contacts

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Eligibility criteria

Inclusion criteria

- women

- age between 30 and 65 years old

- breast carcinoma in the history

- mastectomy in the history

- planned secondary reconstruction by means of a DIEP-flap

Exclusion criteria

- cardiac history (specifically atrial fibrillation and/or cardiac ischemia)

- clotting disorders (deep venous thrombosis or pulmonary embolus in the medical history)

- smoking

- known allergy for dobutamine and/or bisulfite

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2013
Enrollment:	60
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-10-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38526
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4043
NTR-old	NTR4209
CCMO	NL42897.096.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38526

Study results

Summary results
N/A