Argenine suppletie om de reperfusie schade te verminderen en doorbloeding te verbeteren na vrije weefsel transplantaties.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25004

Source
Nationaal Trial Register

Brief title
N/A

Health condition

reperfusion injury, Arginine, free flap surgery

Sponsors and support

Source(s) of monetary or material Support: Plastic Surgery Department, Maastricht University Center of Health. Dutch Burns Foundation

Intervention

Outcome measures

Primary outcome

Partial flap loss (result of insufficient bloodflow).

Secondary outcome

Laser doppler flow (microcirculation measurement).

Study description

Background summary

Partial flap loss due to microvascular failure is first initiated by the incapability of the vascular pedicle to provide sufficient microvascular perfusion in distal segments of the flap. In addition, in free flap surgery the entire flap is affected by ischemia reperfusion injury. The distal segments in free flap surgery are particular vulnerable for ischemia reperfusion injury, and are thus primarily affected by ischemia reperfusion injury which may lead to distal partial flap loss.
Nitric oxide (NO) has been the focus in an extensively amount of studies regarding its use in reducing the IR-injury. It is widely accepted that the L-Arginine-Nitric Oxide pathway plays a pivotal role in the pathophysiology of IR-injury. L-Arginine, the sole precursor of NO, can be metabolized in NO and citruline by a family of tree isoforms of NO synthase (NOS). Endothelial NOS (eNOS) and neuronal NOS (nNOS), these are mainly constitutively expressed by respectively endothelial cells and neuronal cells. Expression of inducible NOS (iNOS) is induced by inflammatory mediators and is mainly expressed in leucocytes. L-Arginine has shown to scavenge free radicals which are expressed during reperfusion. Its end product NO is an important and potent vasodilatator and prevents aggregation and activation of neutrophils and platelets. Furthermore NO concentrations are reduced during ischemia and production remains low after reperfusion. Therefore increasing NO production by stimulating the L-Arginine-NO pathway may lessen the severity of IR-injury. In experimental studies intravenous L-Arginine substantially reduces ischemia-reperfusion injury in cutaneous and musculocutaneous flaps. The purpose of this translational study was to establish the possible protective effect of L-arginine on microvascular perfusion and clinical outcome in free flap surgery.

Study objective

L-arginine, a precursor of NO, reduces ischemia-reperfusion injury and increases microcirculatory bloodflow. This will lead to a reduction of complications in free flap surgery.

Study design

1. After flap dissection;

2. ischemia;

3. reperfusion;

4. 1,2,3,4,5 hours after reperfusion;

5. 1 week outpatient clinic;

6. 6 week outpatient clinic.

Intervention

Patients received intravenously one liter of either L-arginine (verum group, 30 g L-arginine-HCl / 1L 0.9% NaCl) or an Alanine (placebo group, 25.2 g Alanine / 1L 0.9% NaCl) during a 24 hour period.

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Eligibility criteria

Inclusion criteria

All patients with free TRAM flap breast reconstruction.

Exclusion criteria

Previous midline laparotomy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2003
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	13-01-2009
Application type:	First submission

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
NTR-new	NL688
NTR-old	NTR1626
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

1. Debats IB, Booi DI, Deutz NE, Buurman WA, Boeckx WD, van der Hulst RR. Infected chronic wounds show different local and systemic arginine conversion compared with acute wounds. J Surg Res. 2006 Aug;134(2):205-14.
2. Booi DI, Debats IB, Boeckx WD, van der Hulst RR. Risk factors and blood flow in the free TRAM flap: Smoking and high flap weight impair the free TRAM flap microcirculation. Ann Plast Surg. 2007 Oct; 59(4):364-71
3. Booi DI, Debats IB, Boeckx WD, van der Hulst RR. Laser Doppler Flowmetry in the free TRAM flap when using zone IV: a clinical study indicating a 48 hour delay in choke vessel opening. JPRAS 2008 March; 61(3):282-8
4. Debats IB, Booi DI, Wehrens KWE, Van den Hogen E, Deutz NE, Bemelmans MHA, van der Hulst RR. Oral arginine supplementation and the effect of skin graft donor sites; a randomized clinical pilot study. Accepted for publication in J Burn Care and Res.
5. Booi DI, Wehrens KWE, Lievaart V, Debats IB, Marcus MAE, van der Hulst RR. Peri-operative fluid overload increases postoperative complications in the free TRAM flap. Submitted for publication.