The effect of pre- and postoperative supplemental enteral nutrition in high-risk patiens undergoing elective cardiac surgery. A prospective randomized placebo controlled double blind multicenter trial.

No registrations found.

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

Summary

ID

NL-OMON26142

Source
NTR

Brief title
IMPACT II

Health condition

High risk patients undergoing elective cardiac surgery.

Sponsors and support

Primary sponsor: Academic Medical Centre
Source(s) of monetary or material Support: Novartis Nutrition
Bern
Switzerland

Intervention

Outcome measures

Primary outcome

Postoperative morbidity, e.g. infectious morbidity & organ (dys)function.

Secondary outcome

1. Immunological parameters (inflammatory response);

2. ICU and hospital stay of length.

Study description

Background summary

Preoperative oral immune enhancing nutritional supplement reduces postoperative infectious morbidity and results in a more stable circulation; the addition of glycine does not result in any benificial effect over standard oral immune enhancing nutritional supplement.

Study objective

To study the effects of a pre-operative supplemental enteral feeding with IMPACT® on the systemic inflammatory response to cardiopulmonary bypass and on immunological parameters will be examined.

Study design

N/A

Intervention

All patients receive an oral nutritional supplement for at least 5 days with a maximum of 10 days before their operation in addition to their normal diet. One treatment group received a supplement that was enriched with arginine, omega-3 PUFAs and nucleotides compared to the control. The other
treatment group received a supplement that was further enriched with glycine compared with the first treatment group. Patients that needed enteral nutrition postoperatively received a formula that was comparable with the preoperative supplement.

Contacts

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Eligibility criteria

Inclusion criteria

Patients aged >= 70 years undergoing coronary bypass grafting, or pre-operative fraction < 0.40 or patients undergoing mitral valve replacements or combinations.

Exclusion criteria

1. Age <21 years;

2. Pregnancy;

3. Insulin depedent diabetes mellitus;

4. Hepatic cirrhosis;

5. Known malignancy;

6. Use of chemotherapy, NSAIDs or corticosteroids;

7. Schizophrenia;

8. Severe renal failure;

9. Patients with organ transplantation in the past.

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):	01-05-1996
Enrollment:	74
Type:	Actual

Ethics review

Positive opinion

Date:	06-10-2005
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	NL410
NTR-old	NTR450
Other	: 96.17.066
ISRCTN	ISRCTN37657221

Study results

Summary results
JPEN J Parenter Enteral Nutr. 2007 May-Jun;31(3):173-80.

Abstract NESPEN, december 2004.
