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.

Gepubliceerd: 06-10-2005 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26142

Bron
NTR

Verkorte titel
IMPACT II

Aandoening

High risk patients undergoing elective cardiac surgery.

Ondersteuning

Primaire sponsor: Academic Medical Centre
Overige ondersteuning: Novartis Nutrition
Bern
Switzerland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-05-1996
Aantal proefpersonen:	74
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	06-10-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL410
NTR-old	NTR450
Ander register	: 96.17.066
ISRCTN	ISRCTN37657221

Resultaten

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

Abstract NESPEN, december 2004.
