

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

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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.

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestopt       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## **Samenvatting**

### **ID**

NL-OMON26142

### **Bron**

Nationaal Trial Register

### **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 beneficial 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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## **Wetenschappelijk**

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## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

Patients aged  $\geq$  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 dependent 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        |
| Blinding:        | 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. <br>

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Abstract NESPEN, december 2004.<br>