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# The effect of pre- and post-operative supplemental enteral nutrition in high-risk patients undergoing elective cardiac surgery. A prospective randomised placebo controlled double blind multicentre trial.

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|---|---|---|
| **Submission date**<br>27/01/2006 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>27/01/2006 | **Overall study status**<br>Completed | |
| **Last Edited**<br>26/08/2009 | **Condition category**<br>Surgery | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**
NCT00247793

**Protocol serial number**

NTR450; 96.17.066

# Study information

### Scientific Title

### Acronym
IMPACT II

### Study objectives
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.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Received from local medical ethics committee

### Primary study design
Interventional

### Study design
Multicentre prospective randomised double blind placebo controlled parallel group trial

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
High risk patients undergoing elective cardiac surgery

### Interventions
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 post-operatively received a formula that was comparable with the pre-operative supplement.

### Intervention Type
Procedure/Surgery

### Phase
Not Specified

### Primary outcome(s)
Postoperative morbidity e.g. infectious morbidity and organ (dys)function

### Key secondary outcome(s)
Immunological parameters (inflammatory response)
ICU and hospital stay of length

### Completion date
01/11/1997

## Eligibility

### Key inclusion criteria
Patients aged ≥70 years undergoing coronary bypass grafting, or pre-operative fraction <0.40 or patients undergoing mitral valve replacements or combinations

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Senior

### Sex
All

### Key exclusion criteria
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

### Date of first enrolment
01/05/1996

### Date of final enrolment
01/11/1997

## Locations

### Countries of recruitment
Netherlands

### Study participating centre

**Academic Medical Center**
Amsterdam
Netherlands
1105 AZ

# Sponsor information

**Organisation**
Academic Medical Centre (AMC) (Netherlands)

**ROR**
https://ror.org/03t4gr691

# Funder(s)

**Funder type**
Industry

**Funder Name**
Novartis (Switzerland)

**Alternative Name(s)**
Novartis AG, Novartis International AG

**Funding Body Type**
Government organisation

**Funding Body Subtype**
For-profit companies (industry)

**Location**
Switzerland

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
| --- | --- | --- | --- | --- | --- |
| Results article | results | 01/09/2001 | | Yes | No |