

# 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.

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/08/2009	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Robert Tepaske

**Contact details**  
Academic Medical Center  
Department of Intensive Care, C3-324  
P.O. Box 22660  
Amsterdam  
Netherlands  
1105 AZ  
r.tepaske@amc.uva.nl

## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00247793

**Protocol serial number**

## 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

### Study design

Multicentre prospective randomised double blind placebo controlled parallel group trial

### Primary study design

Interventional

### 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  $\geq 70$  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?
<a href="#">Results article</a>	results	01/09/2001		Yes	No