

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00247793

Secondary identifying numbers

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

Study design

Multicentre prospective randomised double blind placebo controlled parallel group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**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 measure

Postoperative morbidity e.g. infectious morbidity and organ (dys)function

Secondary outcome measures

Immunological parameters (inflammatory response)

ICU and hospital stay of length

Overall study start date

01/05/1996

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

Age group

Senior

Sex

Both

Target number of participants

74

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)

Sponsor details

Department of Intensive Care

P.O. Box 22660

Amsterdam

Netherlands

1105 AZ

Sponsor type

Hospital/treatment centre

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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 |