ISRCTN37657221 https://doi.org/10.1186/ISRCTN37657221

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.

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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