

# The effect of nutrition in cardiac surgical patients on heart function.

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We hypothesize that there is a disturbed amino acids profile in the cardiac surgical patient and that nutrition during surgery will normalize this profile with a subsequent improvement in cardiomyocytes functioning by histology, and in cardiac...

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20597

### Source

NTR

### Health condition

Coronary artery disease, heart failure. Coronair lijden, hartfalen.

## Sponsors and support

**Primary sponsor:** Academic Medical Center University of Amsterdam

**Source(s) of monetary or material Support:** Financial: Private resources.

Material: B.Braun (Oss, The Netherlands) and DSM (Delft, The Netherlands).

## Intervention

## Outcome measures

### Primary outcome

The main study outcomes are concentrations of amino acids, and methylated arginines in blood plasma and cardiac tissue, and cardiomyocytes functioning assessed by histology.

## Secondary outcome

The secondary study outcomes are cardiac perfusion, and cardiac fatty acid and glucose metabolism, measured by myocardial scintigraphy and positron emission tomography.

## Study description

### Background summary

#### Rationale:

Malnutrition is very common in patients undergoing cardiac surgery as well as other types of surgery. For example, in a population of cardiac and abdominal surgical patients, respectively 9.1% and 44% was malnourished. Malnutrition can change myocardial substrate utilization which can induce adverse effects on myocardial metabolism. Interestingly, malnutrition is an underlying risk factor for the perioperative cardiac complications seen in patients undergoing non-cardiac surgery. Therefore, by optimizing nutritional status of (cardiac) surgical patients, cardiac metabolism and function might be improved. This can be done by administration of enteral or parenteral feeding.

#### Objective:

Our primary objective is to evaluate the effect of perioperative enteral and peripheral parenteral nutrition on amino acid profile and cardiomyocytes functioning of cardiac surgical patients. Our secondary objective is to study the effect of (par)enteral nutrition on cardiac perfusion, and fatty acid and glucose metabolism. We hypothesize that there is a disturbed amino acids profile in the cardiac surgical patient and that nutrition during surgery will normalize this profile with a subsequent improvement in cardiomyocytes functioning by histology, and in cardiac perfusion and metabolism.

#### Study design:

This proof-of-concept will be investigated in a randomized controlled intervention study.

#### Study population:

Our research population will consist of 48 patients undergoing cardiac surgery for coronary artery bypass grafting (CABG) at the department of cardio-thoracic surgery at the Academic Medical Center University of Amsterdam.

#### Intervention:

Our patients will be given enteral nutrition (n=16), peripheral parenteral nutrition (n=16) or a saline solution (control) (n=16) at least three days before, during, and one day after CABG. Both enteral and parenteral nutrition are mixtures of amino acids, glucose, lipids, vitamins, and minerals.

#### Main study parameters/endpoints:

We will illustrate the effect of nutrition by differences in amino acids concentrations in blood

plasma and cardiac tissue, and in cardiomyocytes functioning between the (par)enteral and control group. In addition, differences in cardiac perfusion, and fatty acid and glucose metabolism between the (par)enteral and control group will be evaluated by myocardial scintigraphy with the tracer technetium-99m-tetrofosmin (99mTc-tetrofosmin), by myocardial scintigraphy with beta-methyl-p-[123I]-iodophenyl-pentadecanoic acid (123IBMIPP), and by using positron emission tomography (PET) with the tracer F18-fluorodeoxy-glucose (18FFDG) respectively.

## **Study objective**

We hypothesize that there is a disturbed amino acids profile in the cardiac surgical patient and that nutrition during surgery will normalize this profile with a subsequent improvement in cardiomyocytes functioning by histology, and in cardiac perfusion and metabolism.

## **Study design**

Blood samples will be taken before, during and after surgery. Cardiac tissue samples will be collected during surgery. Myocardial scintigraphy, and a PET-scan will be performed at baseline and 3 weeks after surgery.

## **Intervention**

Our patients will be given enteral nutrition (n=16), peripheral parenteral nutrition (n=16) or a saline solution (control) (n=16) at least three days before, during, and one day after CABG. Both enteral and parenteral nutrition are mixtures of amino acids, glucose, lipids, vitamins, and minerals.

## **Contacts**

### **Public**

P.O. Box 22700  
B.A.J.M. Mol, de  
Amsterdam 1100 DE  
The Netherlands  
+31 (0)20 5666088

### **Scientific**

P.O. Box 22700  
B.A.J.M. Mol, de  
Amsterdam 1100 DE  
The Netherlands  
+31 (0)20 5666088

# Eligibility criteria

## Inclusion criteria

1. Patients who have to undergo an off-pump coronary artery bypass grafting (CABG) operation;
2. Aged 18 till 81 years.

## Exclusion criteria

1. Combined valve and CABG procedures;
2. Aged <18 and > 80 years;
3. Diabetes mellitus type I;
4. Pregnancy;
5. Renal insufficiency defined as creatinine > 95 micromol/L for women and > 110 micromol/L for men;
6. Liver insufficiency defined as alanine aminotransferase > 34 U/l for women and > 45 U/l for men.

# Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2010
Enrollment:	48
Type:	Actual

## Ethics review

Positive opinion

Date: 26-01-2010

Application type: First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 36742

Bron: ToetsingOnline

Titel:

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
NTR-new	NL2066
NTR-old	NTR2183
CCMO	NL28231.018.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36742

## Study results

### Summary results

N/A