# 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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

# Samenvatting

#### ID

NL-OMON20597

**Bron** NTR

#### Aandoening

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

#### Ondersteuning

**Primaire sponsor:** Academic Medical Center University of Amsterdam **Overige ondersteuning:** Financial: Private resources. Material: B.Braun (Oss, The Netherlands) and DSM (Delft, The Netherlands).

#### **Onderzoeksproduct en/of interventie**

#### **Uitkomstmaten**

#### Primaire uitkomstmaten

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

# **Toelichting onderzoek**

#### Achtergrond van het onderzoek

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 technium99m-tetrofosmine (99mTc-tetrofosmine), 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.

#### Doel van het onderzoek

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.

#### Onderzoeksopzet

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.

#### **Onderzoeksproduct en/of interventie**

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.

# Contactpersonen

#### **Publiek**

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## Wetenschappelijk

P.O. Box 22700 B.A.J.M. Mol, de Amsterdam 1100 DE

# **Deelname eisen**

# Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients who have to undergo an off-pump coronary artery bypass grafting (CABG) operation;

2. Aged 18 till 81 years.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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/I for women and > 45 U/I for men.

# Onderzoeksopzet

# Opzet

Type: Onderzoeksmodel: Toewijzing: Interventie onderzoek Parallel Gerandomiseerd

4 - The effect of nutrition in cardiac surgical patients on heart function. 1-05-2025

Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

### Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-04-2010
Aantal proefpersonen:	48
Туре:	Werkelijke startdatum

# **Ethische beoordeling**

Positief advies	
Datum:	26-01-2010
Soort:	Eerste indiening

# **Registraties**

# Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36742 Bron: ToetsingOnline Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

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

5 - The effect of nutrition in cardiac surgical patients on heart function. 1-05-2025

# Resultaten

## Samenvatting resultaten

N/A