

# TripleFive Pilot Study investigating the feasibility and initial safety of the (L)IMA bed application of ACF-Matrix haemostat in 10 CABG patients

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In a small pilot study to investigate possible occurrence of blood chemistry deviations and / or a tamponade after the application of ACF-Matrix haemostat in the (L)IMA bed.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Coronary artery disorders
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33928

### Source

ToetsingOnline

### Brief title

TripleFive Pilot Study

### Condition

- Coronary artery disorders

### Synonym

coronary artery disease; atherosclerosis coronary arteries

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Gelita Medical BV

**Source(s) of monetary or material Support:** Gelita Medical BV

## Intervention

**Keyword:** (L)IMA-bed, ACF-Matrix, bypass, safety

## Outcome measures

### Primary outcome

- the possible occurrence of abnormalities in blood chemistry
- the possible occurrence of tamponade

### Secondary outcome

n.a.

## Study description

### Background summary

Haemostatic gelatin sponges in general have not been applied in the (L)IMA bed during CABG operations, nor has the haemostatic gelatin sponge ACF-Matrix haemostat in particular been applied in these operations.

Haemostatic gelatin sponges have successfully and without (major) side effects been applied in over 100 million operations over the last 10 years.

Nevertheless, we are of the opinion that a small pilot study to investigate possible occurrence of blood chemistry deviations and / or a tamponade after the application of ACF-Matrix haemostat is appropriate.

### Study objective

In a small pilot study to investigate possible occurrence of blood chemistry deviations and / or a tamponade after the application of ACF-Matrix haemostat in the (L)IMA bed.

### Study design

10 patients that have to undergo an elective CABG operation will be asked by the outpatient doctor to participate in this study. If they agree, 1 day before the operation the patients will have to sign an Informed Consent form.

During the (routine) operation, the only deviation from the hospital protocol will be the application of ACF-Matrix haemostat in the (L)IMA-bed. All other procedures are according to the hospital protocol.

12 -24 hours after the operation, (routine) blood chemistry will be assessed to

investigate if any abnormalities can be found.

In order to recognise signs and symptoms of tamponade within the first 28 days post operative, it will be explained to patients what these signs and symptoms can be: hypotension, tachycardia, tachypnea, distended neck veins, cool extremities with diminished peripheral pulses, decreased urine output and restlessness. In case patients suspects they have 1 or more of these symptoms, they are advised to immediately contact the hospital.

## **Intervention**

ACF-Matrix haemostat is a gelatin sponge with haemostatic action and will be applied in the (L)IMA-bed after removal of the "donor" artery.

## **Study burden and risks**

The expected burden for the patient is minimal. When, as expected, there will be no signs of tamponade, the total burden in time will be approximately 45 minutes.

The risk for the patient of the application of ACF-Matrix haemostat is expected to be minimal since in the past decade over 100 million haemostatische gelatine sponges have been applied successfully in several surgical indications without giving rise to any (major) side effects.

## **Contacts**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Patients 18 years of age or older;
- Patients showing signs and symptoms of coronary ischemia and/or stenosis who are clinically fit to undergo a CABG operation;
- The investigator is satisfied patients have no other ailments that could prevent patients from finishing the study.

### Exclusion criteria

- Patients requiring an acute CABG operation;
- Patients participating in another clinical trial;
- Patients with a local or systemic infection requiring intravenous administration of antibiotics;
- Patients with an allergy to porcine products

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

### Recruitment

NL

Recruitment status: Will not start

Start date (anticipated):	01-01-2009
Enrollment:	10
Type:	Anticipated

## Medical products/devices used

Generic name:	haemostatic gelatin sponge
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	09-03-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

## Study registrations

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

No registrations found.

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

No registrations found.

## In other registers

Register	ID
CCMO	NL25911.068.08