TripleFive Pilot Study investigating the feasibilty 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 occurence of blood chemistry deviations and / or a tamponade after the application of ACF-Matrix haemostat in the (L)IMA bed.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Coronary artery disorders
Study type	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 opartaions, nor has the haemostatic gelatin sponge ACF-Matrix haemostat in particular been applied in these operations.
Haemostatic gelatin sponges have succesfully 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 occurence 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 occurence 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 form 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 partcipating 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