TripleFive Pilot Study investigating the feasibility and initial safety of the application of the haemostatic sponge ACF-Matrix haemostat in 10 Coronary Artery Bypass Grafting patients.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22988

Source
NTR

Brief title
TripleFive Pilot

Health condition

CABG surgery

Sponsors and support

Primary sponsor: Gelita Medical
Source(s) of monetary or material Support: Gelita Medical

Intervention

Outcome measures

Primary outcome

No unexpected post operative events in blood chemistry and no clinical signs and symptoms of tamponade.

Secondary outcome

Reduced post operative blood and fluid loss produced by the drains.

Study description

Background summary

N/A

Study objective

The application of the haemostatic device, ACF-matrix haemostat will reduce blood and fluid loss from the LIMA bed after CABG surgery.

Study design

1. Blood chemistry: < 24 h post-op;

2. Tamponade: < 4 weeks post-op.

Intervention

Application of ACF-Matrix haemostat in the LIMA bed during CABG surgery.

Contacts

Public
A.M. Bijlstra
Gelita Medical BV
Osdorperweg 590
Amsterdam
The Netherlands
+31 (0)20-6675330
Scientific
A.M. Bijlstra
Gelita Medical BV
Osdorperweg 590

Amsterdam
The Netherlands
+31 (0)20-6675330

Eligibility criteria

Inclusion criteria

1. Patients 18 years or older;

2. Patients demonstrating signs and symptoms of coronary ischaemia and/or stenosis clinically considered suitable for correction by CABG surgery;

3. Investigator is satisfied that there are no other physical conditions present which would prevent the patient from entering and completing the Study;

4. Patients who are willing to participate in the proposed Study as evidenced by signing an informed consent form.

Exclusion criteria

1. Patients coming in for an emergency CABG procedure;

2. Patients coming in for a re- CABG procedure;

3. Patients participating in another clinical trial;

4. Patients showing clinical signs of local or systemic infection, requiring (immediate intravenous) treatment with antibiotics;

5. Patients suffering from blood coagulation disorders;

6. Known presence of any disease or medical condition which may affect the wound healing process of the target wound (e.g. malignancy, vasculitis, connective tissue disease, immunological disorder);

7. A very poor life expectancy of less than 12 weeks, according to the investigator’s judgement;

8. Known allergy to porcine products;

9. Any physical or mental state that precludes ability to abide by Study criteria;

10. Patients not able to give consent, subsequent to initial informed consent;

11. The patient is pregnant or a nursing mother;

12. Evidence of chronic alcohol or drug abuse.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2009
Enrollment:	10
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL1590
NTR-old	NTR1670
Other	: Gelita Medical
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A