The Fibrin Induced Blood Exposure Reduction (FIBER) Study: A multi-center, randomized controlled clinical trial to investigate the cost-effectiveness of Fibrin Sealant in CABG surgery

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28163

Source
Nationaal Trial Register

Brief title
FIBER

Health condition

Fibrin Sealant
CABG surgery
blood transfusion
cost-effectiveness

Sponsors and support

Primary sponsor: J.A. van Hilten, PhD
Corporate Staff
Sanquin Blood Bank
Plesmanlaan 1a
2333 BZ Leiden
Phone: 071 568 5060

Joost.vanHilten@sanquin.nl
Source(s) of monetary or material Support: ZonMw
Sanquin Blood Bank

Intervention

Outcome measures

Primary outcome

Efficacy:

Total amount of blood products used within 48 hrs after surgery

Costs:

Length of ICU stay

Secondary outcome

Efficacy:

- Blood loss

- Reoperation for bleeding

- Wound infection

- Mortality

Costs:

- Length of hospital stay

Study description

Study objective

The use of Fibrin Sealant (FS) in CABG surgery will reduce the amount of transfusions required within 48 hrs after surgery as well as the length of ICU stay.

Study design

- First 48 hrs after surgery

- End ICU stay

- Discharge

Intervention

Patients are randomly assigned to receive either FS treatment, up to a maximum of 15 ml FS per patient, or no FS treatment

Contacts

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Eligibility criteria

Inclusion criteria

1. Elective, isolated CABG surgery with the use of at least one internal thoracic artery

2. Age >18 years

Exclusion criteria

1. Exclusive use of venous grafts

2. Any concomitant procedure, including AF ablation

3. Emergency surgery

4. History of bleeding diathesis or coagulopathy

5. Jehova’s witness

6. Participation in any study involving an investigational drug or device

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

Control: Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2008
Enrollment:	1500
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-07-2008
Application type:	First submission

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	NL1326
NTR-old	NTR1386
CCMO	NL21390.058.08
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A