The use of fibrin sealant in CABG surgery. A pilot study.

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Is the application of allogeneic fibrin sealant in CABG surgery feasible and effective in stopping bleedings/restore hemostasis after restoring the blood flow?

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30606

Source
ToetsingOnline

Brief title
Fibrin sealant in CABG surgery

Condition

- Other condition
- Coronary artery disorders

Synonym
coronary artherosclerosis, stenosis of cardiac arteries

Health condition

bloedingen

Research involving
Human

Sponsors and support

Primary sponsor: Stichting Sanquin bloedvoorziening
Source(s) of monetary or material Support: Sanquin blood supply

Intervention

Keyword: Bleedings, Blood transfusion, CABG surgery, Fibrin sealant

Outcome measures

Primary outcome

Numbers of bleedingstops/complete hemostasis, at least 5 minutes after

restoration of the blood flow.

Secondary outcome

Number of anastomoses

Number of bleedings stopped

Nummer of bloedtransfusies

Amounts of ml fibrin sealant applied

Study description

Background summary

Sanquin blood supply has been engaged by ZonMw to submit a research proposal of a multi-centre randomised controlled trial (RCT) to study the costeffectiveness of CryoSeal (fa. Thermogenesis) fibrin sealant in bypass surgery in the Dutch Health Care. Before applying, Sanquin wants to demonstrate in CABG surgery the feasibility and effectiveness of fibrin sealant composed of allogenous plasma from blood donors.

Study objective

Is the application of allogeneic fibrin sealant in CABG surgery feasible and effective in stopping bleedings/restore hemostasis after restoring the blood flow?

Study design

Observationeel clinil trial of patients who are undergo CABG (coronairy bypass)surgery. Coagulation times are registrered starting at the moment the fibrin sealant is applied, in addition to registration of the amounts of fibrin sealant used, number of bypasses, duration on-pump, number of bleedings stopped and given transfusions.

Study burden and risks

nihil to very low additional risks

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

CABG patients with a minimum age of 18 years
Revisions of CABG

Exclusion criteria

Patients with congenital or acquired coagulation deseases
Patients with thrombopenia, < 100 x 10*9 PLT/L

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-01-2007
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL15994.058.07