Degradation speed of an autologous fibrin clot administered to the pericardial sac.

Published: 27-09-2007
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Find out whether fibrin clots applied to the pericardial sac might be suitable drug-delivery systems.

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

Summary

ID

NL-OMON30983

Source
ToetsingOnline

Brief title
Intrapericardial fibrin clot degradation.

Condition

- Other condition

Synonym
er wordt niet naar ziekten/aandoeningen gekeken.

Health condition

er wordt slechts gekeken naar normale fysiologie, niet naar aandoeningen/ziekten.

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: bedrijven

Intervention

Keyword: autologous, fibrin clot, fibrinolysis, intrapericardial

Outcome measures

Primary outcome

Fibrin clot weight after 60 minutes of intrapericardial incubation

(specifically: clot weight reduction compared to starting clot weight).

Secondary outcome

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Study description

Background summary

Within medicine, e.g. ENT, plastic surgery, autologous fibrin clots have been used as slow-release drug delivery systems. The pericardial sac has proven to be a site for local therapy for heart and coronaries. Therapeutics become available when fibrinolysis degrades the fibrin clots. In order to serve as a slow-release drug delivery system, fibrin clots need to be able to survive in the pericardial sac for a couple of days. Fibrin degradation characteristics when applied to the pericardial sac are currently largely unknown.

Study objective

Find out whether fibrin clots applied to the pericardial sac might be suitable drug-delivery systems.

Study design

Observational study without invasive measurements.

Study burden and risks

Naar onze mening brengt het bovenbeschreven observationeel onderzoek geen risico*s voor de patiënt met zich mee. Tijdens reguliere hartchirurgie loopt vaak een beperkte hoeveelheid vers bloed (enkele tientallen ml.*s) uit het operatiegebied in het hartzakje. Dit is inherent aan de procedure die plaatsvindt en brengt voor de patiënt geen risico*s met zich mee voor wat betreft beperking van hartfunctie.

De operatieduur zal door deze observationele studie niet worden verlengd.

As indicated above, to our opinion, no additional risks are associated with this observational study. Furthermore, the observation will not result in time loss during the cardiac surgery.

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

All patients undergoing coronary artery bypass grafting and/or valve surgery via sternotomy.

Exclusion criteria

previous cardiac surgery.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2007
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	27-09-2007
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	NL17443.068.07