Comparison of celite activated clotting time with kaolin activated clotting time during cardiac surgery.

Published: 19-12-2007
Last updated: 24-08-2024

We want to compare duplicate measurements of celite ACT and kaolin ACT in patients undergoing cardiac surgery. In addition we want to measure heparin use during surgery in patients monitored with celite ACT and with kaolin ACT.In addition,...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Therapeutic procedures and supportive care NEC
Study type	Observational non invasive

Summary

ID

NL-OMON39708

Source
ToetsingOnline

Brief title
ACT during cardiac surgery.

Condition

- Therapeutic procedures and supportive care NEC

Synonym
activated clotting time, anti-coagulation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: activated clotting time, cardiac surgery, celite, kaolin

Outcome measures

Primary outcome

the total amount of heparin given in each group.

Secondary outcome

fibrinopeptide A and postoperative blood loss

Study description

Background summary

Anticoagulation during cardiac surgery is point of care monitored using the activated clotting time (ACT) as described by Bull [1]. As an activator for this measurement either celite or kaolin is used. Both activators are used routinely in clinical practice. However, there is doubt about the reliability of each measurement. In addition, a review of patient charts suggests that kaolin ACT has less variability than celite ACT.

Study objective

We want to compare duplicate measurements of celite ACT and kaolin ACT in patients undergoing cardiac surgery. In addition we want to measure heparin use during surgery in patients monitored with celite ACT and with kaolin ACT.
In addition, preliminary data suggest that platelet function influences ACT measurements.
Additionally, platelet function will be monitored by means of aggregometry to reveal how this influences the ACT values

Study design

Randomized prospective single blinded clinical trial. 125 Patients are allocated to either group one(n50): heparin management is guided by celite act or group two(n50): heparin management is guided by kaolin act.
group3(25) ADDITIONAL HEPARIN MANAGEMENT IS GUIDED BY Junior measurements

Study burden and risks

in total 49mL blood will be taken from the heart lung machine.
There are no risks associated with participation as both monitoring measurements are routinely used during cardiac surgery.
Patients will not individually benefit from participation.

Contacts

Public
Universitair Medisch Centrum Groningen

hanzeplein 1 hanzeplein 1
Groningen 9700RB
AF
Scientific
Universitair Medisch Centrum Groningen

hanzeplein 1 hanzeplein 1
Groningen 9700RB
AF

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients presenting for coronary artery bypass grafting and/or valve repair/replacement.

Exclusion criteria

Patients with heredetary coagulopathies. Patients pre-operatively treated with unfractionated heparin.

Study design

Design

Study type: Observational non invasive

Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-03-2008
Enrollment:	125
Type:	Actual

Ethics review

Approved WMO

Date:	19-12-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	11-05-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL17568.042.07