Een vergelijking van twee meetmethoden voor de mate van ontstolling gedurende cardiopulmonale bypass tijdens hartchirurgie.

No registrations found.

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

Summary

ID

NL-OMON29162

Source
Nationaal Trial Register

Brief title
ACT-studie

Health condition

Kaolin, Celite, Heparin, Cardiopulmonary bypass, Cardiac surgery.

Sponsors and support

Primary sponsor: institutional
Source(s) of monetary or material Support: intsitutional

Intervention

Outcome measures

Primary outcome

Total heparin use at the end of CPB.

Secondary outcome

1. Fibrinopeptide A concentration;

2. Postoperative chest tube loss;

3. Use of blood and blood products;

4. Length of stay in the intensive care unit.

Study description

Background summary

Rationale:

During cardiac surgery a sufficient anticoagulation is necessary for the period of cardiopulmonary bypass (CPB). Heparin is used for this purpose. Anticoagulation is point of care monitored using the activated clotting time (ACT) as described by Bull [1]. As activator for this measurement either celite or kaolin is used. Both activators are used routinely in clinical practice. In this hospital both measurements are also used. However, there is doubt about the consequences of heparin management using these measurements. Moreover, a review of patient charts suggests that kaolin ACT has less variability than celite ACT.

Objective:

In this study we will therefore measure total heparin use and the concentration of fibrinopeptide A at the end of CPB, using either celite ACT or kaolin ACT guided heparin management. In addidtion clinical parameters as chest tube loss, blood use, and length of stay in the intensive care unit will be measured. We propose this study also to compare duplicate measurements of celite ACT with duplicate measurements of kaolin ACT in patients undergoing cardiac surgery.

Study design:
Prospective randomized clinical trial.

Study population:
Patients presenting for cabg and/or valve reair/replacement. Excluded are patients with heredetary coagulopathies, patients pre-operatively treated with unfractionated heparin, patients less than 18 years old.

Intervention:
Group one: heparin management for CPB is guided by celite ACT.

Group two: heparin management for CPB is guided by kaolinACT.

Main study parameters/endpoints:
Primary: the total amount of heparin given in each group.
Secondary: Fibrinopeptide A concentration; postoperative chest tube loss, use of blood and blood products, and length of stay in the intensive care unit.

Study objective

We recently found that the longterm use of aspirin resulted in lower celite-ACT during cardiopulmonary bypass (CPB). The ACT is routinely measured in duplicate. A review of patient charts suggests that kaolin-ACT has less variability than celite ACT. We hypothesize that kaolin guided ACT management results in less heparin use.

Study design

After induction of anesthesia baseline ACT is measured. Heparin is given before CPB as usual (300IU/kg). After 3 min ACT is measured as usual. If ACT<400s addiitonal heparin (100IU/kg) is given. 5 min after start CPB and then after every 30 min ACT is measured as usual. If ACT<400s addiitonal heparin (100IU/kg) is given according to our clinical practice. After CPB the heparin is neutralized with protamine in a 1:1 ratio as usual.

Intervention

Group one: heparin management is guided by celite-ACT.

Group two: heparin management is guided by kaolin-ACT.

To measure the actual heparin concentration a duplicate HiTT (high dose thrombin time) measurement will also be perfomed (3mL).

Additional measurements:

1. Preoperative and postoperative antithrombin-3 (3mL);

2. End cpb fibrinopeptide a (3mL);

3. Postoperative chest tube loss;

4. Use of blood and bloodproducts;

5. Length of stay in the ICU.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

Excluded are patients with heredetary coagulopathies, patients pre-operatively treated with unfractionated heparin, patients treated with aprotinin, and patients less than 18 years old.

Study design

Design

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

Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2008
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-03-2009
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	NL1640
NTR-old	NTR1738
Other	MEC UMCG : 2007.124
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A