Evaluating point-of-care prothrombin time measurements for cardiac surgery

Published: 19-03-2014
Last updated: 24-04-2024

Ex vivo study: What is the relation between increasing heparin concentrations and different protamine:heparin-ratio*s with POC-PT values in blood drawn from healthy volunteers?Clinical study in cardiac surgery: Does the POC-PT device correspond with...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON40525

Source
ToetsingOnline

Brief title
POC-PT study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Cardiac therapeutic procedures

Synonym
coagulation status, prothrombin time

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cardiac surgery, Hemostasis, Point-of-care, Prothrombin time

Outcome measures

Primary outcome

The International Normalized Ratio (INR) of the prothrombin time (PT) as

measured with Coaguchek Plus or routine laboratory tests.

Secondary outcome

The ex vivo effect of different protamine:heparin ratio on the POC-PT.

Study description

Background summary

After cardiac surgery information about the coagulation status is required to know if the patient is suspected for coagulopathy. The value of routine laboratory coagulation tests in this setting is restricted by their extensive turnaround times, which estimate 30-60 minutes. The point-of-care (POC) coagulation monitoring device, Coaguchek Pro, which measures the prothrombin time (PT) within 3 minutes, may overcome this limitation. Only a few studies have evaluated the device in patients undergoing cardiac surgery.
During cardiac surgery patients receive heparin prior to cardiopulmonary bypass (CPB) to prevent the blood to clot in the extracorporeal circulation. In addition, after weaning from CPB, heparin is reversed by protamine, which in itself acts as an anticoagulant if administered in excess. Due to these factors, which significantly influence hemostasis, coagulation monitors have to be separately validated for their use after CPB. Therefore we aim to evaluate the effect of different heparin concentrations and protamine-heparin ratio*s on the POC-PT in an in vitro setting in blood from healthy volunteers. The second aim of our study is to investigate the optimal timing for POC-PT testing after protamine administration.

Study objective

Ex vivo study:
What is the relation between increasing heparin concentrations and different protamine:heparin-ratio*s with POC-PT values in blood drawn from healthy volunteers?

Clinical study in cardiac surgery:
Does the POC-PT device correspond with the classical laboratory prothrombin time before cardiopulmonary bypass and 3, 6 and 10 minutes following protamine administration in patients undergoing elective cardiac surgery with cardiopulmonary bypass?

Study design

Prospective, single center, observational study in the VUmc

Study burden and risks

There are no serious adverse events expected since all procedures are standard clinical care and do not comprise an intervention that may harm the volunteer or patient. In total 20 mL blood will be drawn from volunteer or patient.

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

Ex-vivo study
- Healthy volunteers
- Age 18 * 90 years
- Informed consent;Clinical study in cardiac surgery
- Patients undergoing elective cardiothoracic surgery
- Age 18-90 years
- Preoperative hemoglobin of > 5.5 mmol/l
- Informed consent

Exclusion criteria

Ex vivo study
- Subjects with hemostatic deficiencies or previous hemostatic problems
- Subjects using vitamin K antagonists, clopidogrel or dabigatran at the time of surgery.
- Pregnancy;Clinical study in cardiac surgery
- Re-operations and emergency operations
- Use of erythropoietin
- Hepatic or renal failure

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-04-2014
Enrollment:	64

Type:	Actual

Medical products/devices used

Generic name:	Point-of-care prothrombin time
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-03-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL43303.029.13