Heparin management and hemostatic risk evaluation in patients undergoing pulmonary thrombo-endarterectomy

Published: 01-10-2015
Last updated: 20-04-2024

To provide evidence demonstrating that ACT-guided heparin management during pulmonary thrombo-endarterectomy (PTE) involving cardiopulmonary bypass (CPB) and deep hypothermic circulatory arrest (DHCA) will result in inadequate heparinization and...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Pulmonary vascular disorders
Study type	Observational invasive

Summary

ID

NL-OMON42520

Source
ToetsingOnline

Brief title
PTE study

Condition

- Pulmonary vascular disorders
- Vascular therapeutic procedures
- Embolism and thrombosis

Synonym
Chronic pulmonary embolism; Pulmonary hypertension

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: Cardiopulmonary bypass, Chronic longembolism, Pulmonary hypertension, Thrombo-endarterectomy

Outcome measures

Primary outcome

Perioperative changes in the activated clotting time (ACT) and heparin

concentration

Secondary outcome

Perioperative changes in thromboelastometric parameters and platelet

aggregation

Study description

Background summary

Incomplete resolution of pulmonary embolism (PE) can result in a condition known as chronic thromboembolic pulmonary hypertension (CTEPH), which is characterized by increased pulmonary vascular resistance, pulmonary hypertension and eventually right heart failure. The surgical intervention for CTEPH is called pulmonary thrombo- endarterectomy (PTE) or pulmonary endarterectomy (PEA), a procedure that requires cardiopulmonary bypass (CPB) and deep hypothermic circulatory arrest (DHCA). To prevent thrombin generation from occurring, the anticoagulant heparin is administered to the patient prior and during CPB and the activated clotting time (ACT) is used to monitor anticoagulation. However, the ACT may be artificially prolonged during CPB because of hemodilution and hypothermia and it is unknown whether DHCA during PTE procedures may result in inadequate heparinization and consequently hemostatic activation. Since the majority of CTEPH patients show an altered hemostatic profile, this might increase their risk for thrombotic and/or bleeding complications.

Study objective

To provide evidence demonstrating that ACT-guided heparin management during

pulmonary thrombo-endarterectomy (PTE) involving cardiopulmonary bypass (CPB) and deep hypothermic circulatory arrest (DHCA) will result in inadequate heparinization and consequently an increase in hemostatic activation.

Study design

Single-center, prospective observational study in the VU University Medical Center.

Study burden and risks

A total of 105 ml of extra blood will be drawn from an existing intra-arterial line while the patient is under anesthesia. The intra-arterial line is part of routine clinical care in cardiac surgery, and will therefore not add up to patient discomfort in the present study.

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

• Adult subjects (age 18-85 years)
• Informed consent

Exclusion criteria

• Re-operation
• Hereditary hemoglobinopathies

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):	02-10-2015
Enrollment:	25
Type:	Actual

Medical products/devices used

Generic name:	HepCon Hemostasis Management System / ROTEM thromboelastometry / Multiplatet aggregometer
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-10-2015
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	NL54265.029.15