Coagulation effects of mild therapeutic hypothermia in post cardiac arrest patients.

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We aim to observe in whole blood at patients core temperature and normotemperature how mild therapeutic hypothermia affects coagulation and in particular fibrinogen, in post cardiac arrest patients.

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

Summary

ID

NL-OMON36617

Source
ToetsingOnline

Brief title
Mild hypothermic effects on coagulation.

Condition

- Other condition
- Cardiac arrhythmias

Synonym
Coagulopathy

Health condition

stollingsapparaat

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 arrest, Coagulation, Hypothermia, Thromboelastometry

Outcome measures

Primary outcome

The hypothermic effects on coagulation will be observed by using

thromboelastometry. The main parameters are 1) maximum clot firmness; 2)

clotting time and 3) maximum clot lysis.

Secondary outcome

Not applicable

Study description

Background summary

Mild therapeutic hypothermia (32-34°) improves neurological outcome in patients successfully resuscitated after cardiac arrest. Although hypothermia protects neurologic functions it leads to an unknown degree of impairment of the coagulation.
Infusion with cold crystalloids to induce hypothermia to 33° causes coagulopathy by dilution and causes a decrease in function of platelets. When temperature declines even further non in vivo studies showed that synthesis and kinetics of clotting enzymes, thrombin generation and plasminogen activator inhibitors may be affected. One clinical study showed a slightly prolonged clotting time as sole effect of mild hypothermia on coagulation but measurements were not performed on core temperature therefore causing a possible underestimated of coagulopathy caused by hypothermia. We therefore aim to observe in whole blood at patients core temperature and normotemperature how mild therapeutic hypothermia affects coagulation and in particular fibrinogen, in post cardiac arrest patients.

Study objective

We aim to observe in whole blood at patients core temperature and normotemperature how mild therapeutic hypothermia affects coagulation and in particular fibrinogen, in post cardiac arrest patients.

Study design

Prospective observational, one centre study.

Study burden and risks

In this study we will observe the effects of mild hypothermia on coagulation using thromboelastometry. Fore blood samples of 4.5ml will be used for analysation. Blood sampling will be done from an intravenous catheter witch is standard ICU procedure in all post cardiac arrest patients and will there for not add up to patient discomfort. All other parameters are according to routine ICU protocol and do not cause any extra burden. A potential benefit is the diagnosis of coagulations disorders that are not detected by classical coagulation parameters.

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

In or out of hospital post cardiac arrest patients eligible for hypothermia > 18 years.

Exclusion criteria

< 18 years
Pregnancy
Severe traumatic brain injury
Moribund patients
Use of coumarin derivatives
Pre-existing coagulopathy
Receiving fresh frozen plasma or platelets during hospital admission.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	15-03-2011
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	28-02-2011
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	NL33859.029.10