Hyperfibrinolysis in moderate to severe traumatic brain injury-related coagulopathy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON37358

Source
ToetsingOnline

Brief title
LYSIS-TBI

Condition

- Other condition

Synonym
neurotrauma, Traumatic Brain Injury (TBI)

Health condition

Traumatisch schedelhersenletsel

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: Coagulopathy, Hemostatic dysfunction, Hyperfibrinolysis, Traumatic brain injury

Outcome measures

Primary outcome

- Level of fibrinolysis using rotation thromboelastometry (ROTEM)

- DIC using ISTH DIC scoring system (platelet count, D-dimer, prolonged PT and

fibrinogen level)

- Tissue hemoglobin oxygenation using near infrared spectroscopy (NIRS)

- Endothelial barrier function will be analyzed in an Electric Cell-Substrate

Impedance Sensing (ECIS) system

Secondary outcome

Classical coagulation tests

- Activated partial thromboplastin time (aPTT)

- Hematocrit (Ht), hemoglobin (Hb)

Plasma coagulation parameters:

- Plasma tissue factor antigen

- Fibrin formation

- Thrombin-antithrombin III complex

- D-dimers and E-fragments (fibrin degradation products)

- Activated protein C-protein C inhibitor complex

- Plasminogen activator inhibitor-1 (PAI-1)

- Tissue plasminogen activator (t-PA)

- Thrombin activatable fibrinolysis inhibitor (TAFI)

- Thrombomodulin and thrombin/thrombomodulin complex

Coagulation parameters will be associated with patient demographics, prehospital treatment characteristics, surgical and pharmacological interventions, base deficit (BD), arterial oxygen pressure (pO2), arterial carbon dioxide pressure (pCO2), lactate, pH, fluid management, use of anticoagulants, alcohol abuse, cranial CT scan classification, GCS at the accident scene and upon hospital admission, Revised Trauma Score (RTS) Abbreviated Injury Scale (AIS), Injury Severity Score (ISS), 6-month neurologic and overall patient outcome (Glasgow Outcome Scale (GOS), and 6-month mortality).

Study description

Background summary

Traumatic brain injury (TBI) accounts for a significant proportion of death and disabilities worldwide. The development of coagulation abnormalities in TBI is a complex and serious systemic disorder, which can be characterized by a combination of coagulopathy and hypercoagulability. However, until now, evidence-based diagnostic and treatment strategies for coagulopathy in TBI are lacking.

Study objective

This study aims to gain insight in the in the level of fibrinolysis in patients with traumatic brain injury in the first 24 hours following trauma.

Primairy objective:
- To determine the 24-hour prevalence and course of fibrinolysis in patients with moderate to severe TBI who are admitted to the emergency department (ED) of the VU University Medical Center.
- To determine the relation of these hemostatic abnormalities with regional tissue perfusion.

Secondary objectives
- To determine development of coagulopathy and the association with specific patterns in activated protein C, PAI-1 and TAFI levels.
- To determine the relation of early and delayed coagulopathy with the presence of procoagulant and anticoagulant factors in plasma in moderate to severe TBI.
- To establish the effect of plasma from TBI patients with or without coagulopathy on endothelial barrier function.

Study design

Prospective, observational study in 100 patients with moderate to severe TBI.

Study burden and risks

The burden associated with participation consists of extra blood sampling (3 x 14 ml) from an existing intravenous line and non-invasive tissue oxygenation measurements. Both measurements are associated with a minimal risk and burden for the patients.

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

- Patients with moderate to severe traumatic brain injury
- Glasgow Coma Scale (GCS) score between 3 and 13 upon ED admission
- Age 18-75 years

Exclusion criteria

- Patients with hemostatic deficiencies or previous hemostatic problems
- Prehospital traumatic cardiopulmonary resuscitation
- Emergency surgery in the hour following ED admission
- Absence of a peripheral intravenous catheter
- Patients using vitamin K antagonists, clopidogrel or dabigatran
- Pregnancy

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):	05-09-2012
Enrollment:	100
Type:	Actual

Medical products/devices used

Generic name:	Near-infrared spectroscopy (NIRS)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-08-2012
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	NL39832.029.12