Acute coagulopathy and inflammation of trauma-3

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The Activation of Coagulation and Inflammation in Trauma (ACIT) study is designed to identify the clinically significant mechanisms and pathways by which inflammation and coagulation are activated immediately following major trauma, and how these...

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

Summary

ID

NL-OMON42991

Source
ToetsingOnline

Brief title
ACIT trial

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Injuries NEC
- Respiratory disorders NEC

Synonym
clotting disorder, coagulopathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: EU

Intervention

Keyword: coagulopathy, inflammation, transfusion, trauma

Outcome measures

Primary outcome

28 day mortality

Secondary outcome

Blood transfusion requirement in first 24 hours, length of hospital stay, ICU stay, 28-day ventilator free days, occurrence of acute lung injury (ALI), acute respiratory distress syndrome (ARDS), acute kidney injury (AKI) and multiple organ failure (MOF)

Study description

Background summary

Trauma is the leading cause of death and disability in children and young adults. Over half of all trauma deaths are due to bleeding or the complications resulting from it.[1] Injury, shock and blood loss all contribute to a failure of the body*s normal blood clotting mechanisms (coagulation), which then leads to more bleeding. The mechanisms of these disorders in blood clotting, what initiates them, and how they affect the body are not well understood.

Study objective

The Activation of Coagulation and Inflammation in Trauma (ACIT) study is designed to identify the clinically significant mechanisms and pathways by which inflammation and coagulation are activated immediately following major trauma, and how these result in the observed clinical sequelae of this in terms of bleeding, transfusion requirements, organ injury, multiple organ failure and death.

Study design

Multicenter prospective cohort study.

Study burden and risks

There is no potential benefit for the research participants. The risk to incapacitated adults is no greater than that to adult trauma patients able to give consent, and the study specifically pertains to this group of more severely injured trauma patients. We expect the study to cause a minimum of discomfort to participants.

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

Age > 18 years
Sustained a blunt or penetrating trauma, with at least one of the following clinical

parameters:
o Reparatory rate <10 or >25 times per minute
o Heart rate *120 per minute
o Systolic blood pressure < 90 mmHg
o Oxygen saturation <90%
o Estimated blood loss *500 mL
o GCS * 13 or abnormal pupil size and/or reaction
* Or clinical signs of at least one of the following diagnoses:
o 1 femur fracture
o Signs of flail thorax/pneumothorax/hematothorax or multiple rib fractures
o Signs of significant abdominal injury
o Pelvic fracture
o Spine injury

Exclusion criteria

Age <18
Patients transferred from other hospitals
Patients presenting more than 120 minutes after time of injury
Patients who have received more than 2000 mL of intravenous fluids prior to emergency department arrival
Patients with burns >5% of their body surface area
Patients taking anticoagulant medication other than aspirin (<650mg/day)
Patients with a known bleeding diathesis
Patients with moderate to severe liver disease (Child's classification B or C)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-12-2016

Enrollment:	500
Type:	Actual

Ethics review

Approved WMO Date:	22-11-2016
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	NL58766.018.16