Implementing Treatment Algorithms for the Cure of Trauma Induced Coagulopathy (iTACTIC)

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

Summary

ID

NL-OMON43543

Source
ToetsingOnline

Brief title
iTACTIC trial

Condition

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

Synonym
blood clotting disorder, Coagulopathy

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Europese Commissie onder HEALTH-Contract No. F3-2013-602771

Intervention

Keyword: Coagulopathy, Transfusion, Trauma, Treatment Algorithm

Outcome measures

Primary outcome

The primary endpoint is the proportion of subjects alive and free of massive transfusion at 24 hours.

Secondary outcome

The secondary end points listed below will be analysed in order to provide a sensitive and comprehensive description of outcomes and healthcare resource demands for the intervention and control arm subjects:

* All-cause mortality at 6 and 24-hours and 28 & 90-days post admission.

* Duration and severity of coagulopathy until haemostasis, as defined by the area under the time1 multiplied by PT/INR curve.2,3

* Proportion of patients who have corrected coagulopathy after first 8 units of RBC.

* Time to haemostasis.1

* Time spent in coagulopathic condition until haemostasis.1

* Blood products (RBC, plasma, platelets alone and in total) first 6 and 24 hours after admission

* 28-day ventilator free days.

* 28-day ICU-free days.

* Total hospital length of stay.

* 28-day symptomatic thromboembolic events.

* Incidence of transfusion related complications.

* Incidence of organ dysfunction.

* Health care resource, productivity costs and HRQoL (EuroQol EQ-5DTM at discharge or day 28, and at day 90).

* Lifetime health economic cost-effectiveness of personalized VHA-guided haemorrhagic treatment versus MTP-based on best practice and CCT.

Study description

Background summary

In spite of improved resuscitation strategies, current transfusion therapy still fails to correct coagulopathy during on-going haemorrhage. The mechanisms and genesis of early trauma induced coagulopathy (TIC) have yet to be fully elucidated, and there are many questions around how to optimally diagnose, resuscitate and monitor the critically bleeding trauma patient.
It is important to detect TIC as early as possible. Conventional coagulation tests (CCT), such as prothrombin time/international ratio (PT/INR), activated partial thromboplastin time (APTT), fibrinogen concentration and platelet counts, have traditionally been used. However, there is a striking lack of evidence to support the use of these CCT to monitor resuscitation. Recent published evidence describes an increasing recognition for the potential of Viscoelastic Haemostatic Assays (VHAs), where functional coagulation status of patient whole blood can rapidly and accurately be determined.

Study objective

The primary objective is to compare the haemostatic effect of VHA-guided transfusion strategy versus optimized CCT guided transfusion strategy in haemorrhaging trauma patients. The secondary objectives of the study are to determine the effects of VHA-led versus optimized non-VHA guided resuscitation on organ failure, hospital stay, critical care stay, health care resource needs and mortality.

Study design

Multicentre, non-blinded, randomized controlled trial.

Intervention

Enrolled patients will be block randomized to either study arm:
* CONTROL: Haemostatic resuscitation, based on a MTP aiming at a ratio 1:1:1 of blood components (RBC 1: plasma 1: platelets 1) and CCT to guide further resuscitation with blood products and procoagulant factors.
* INTERVENTION: Haemostatic resuscitation, based on a MTP aiming at a ratio 1:1:1 of blood components (RBC 1: plasma 1: platelets 1) and VHA-guiding further resuscitation with blood products and procoagulant factors.

Study burden and risks

We expect the study to cause a minimum of discomfort to participants. The study hypothesis is that VHA guided treatment is associated with a faster correction of coagulopathy. Thereby, participants in this trial have a possible benefit.

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

- Present with clinical signs of haemorrhagic shock
AND
- Activate the massive haemorrhage protocol and initiate first transfusion
- Randomised within 3 hours of injury and 1 hour of admission to the emergency department
- Informed consent is obtained within 24 hours after injury

Exclusion criteria

- Inclusion criteria are not met
- No informed consent obtained within 24 hours after injury.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-06-2016
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Viscoelastic Haemostatic Assay
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	19-05-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-04-2018
Application type:	Amendment
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	NL56543.018.16