Factor V in traumatic coagulopathy

Published: 23-02-2023
Last updated: 07-04-2024

1. To identify the mechanisms of factor V depletion in an in vitro model of TIC2. To evaluate the effect of FV supplementation either alone or in combination with other coagulation factors in in vitro coagulation tests

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

Summary

ID

NL-OMON53790

Source
ToetsingOnline

Brief title
FITC

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
acute traumatic coagulopathy, Trauma-induced coagulopathy

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Beurzen Anesthesiologie en Intensive Care

Intervention

Keyword: Coagulation, Factor V, Trauma

Outcome measures

Primary outcome

Objective 1

In vitro: what are the factors related to factor V depletion in trauma-induced coagulopathy

Objective 2:

In vitro: whether factor V supplementation either alone or in combination with other factors (PCC and/or fibrinogen) is associated with improvement in clot build-up determined by ROTEM

Secondary outcome

In vitro coagulation will be assessed through multiple methods, for example:

- ROTEM
- Thrombin generation assay
- Platelet function (aggregometry, flow cytometry, adhesion under flow)
- Plasma coagulation proteins
- Blood group, Hb/HCT, platelet count

Study description

Background summary

Severely injured trauma patients present in 40% of cases with a trauma-induced coagulopathy (TIC), composed of severe platelet dysfunction, coagulation factor consumption and hyperfibrino(geno)lysis. It has been shown that factor V among other factors become significantly depleted after trauma. Current treatments include tranexamic acid (antifbrinolytic), transfusion of plasma, platelets and red blood cells in a ratio mimicking the composition of the lost blood,

fibrinogen suppletion, and in specific centres prothrombin complex (II, (VII), IX, X). In animal models supplementation of factor V improves TIC and mortality. Our hypothesis is that supplementation of factor V either alone or in combination with other factors (PCC and/or fibrinogen concentrate) will improve coagulation in an in vitro model of TIC.

Study objective

1. To identify the mechanisms of factor V depletion in an in vitro model of TIC
2. To evaluate the effect of FV supplementation either alone or in combination with other coagulation factors in in vitro coagulation tests

Study design

Type of study: healthy volunteer observational study

We will draw whole blood from 12 male volunteers (age 18-35) at one timepoint. Volunteers will be screened beforehand whether they can participate in this study. Screening will consist of a medical history and current medication use. A qualified and certified person for performing vena puncture will draw blood. Blood will be incubated under various conditions.

Study burden and risks

Benefits: none.
The risks and burden of this study are deemed minor, as venepuncture is a routine procedure in every hospital.

Contacts

Public
Selecteer

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Selecteer

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Male
- Age 18-35

Exclusion criteria

-Participation in a scientific intervention study in the last 3 months
-No informed consent
-History of coagulation disorders
-Active use of prescription medication
-Use of anticoagulant medication, including aspirin
-History of liver disease
-History of chronic transmittable disease
-History of alcohol, smoking or drug abuse

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-05-2023
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	23-02-2023
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	NL82402.018.22