

Understanding clot structure in thrombosis and bleeding disorders

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The aim of this fundamental research is to optimize methods and to investigate the effects of different variables in the human body on the clot structure, contributing to the knowledge of blood clotting, cardiovascular disease, and bleeding...

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

Summary

ID

NL-OMON57046

Source

ToetsingOnline

Brief title

Understanding clot structure in thrombosis and bleeding disorders

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym

bleeding disorder, cardiovascular disease, thrombosis

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Trombose stichting

Intervention

Keyword: Clot characteristics, Fibrin, Flow, Haemostasis

Outcome measures

Primary outcome

In this fundamental research project, we study determinants of the clot structure and how they affect the clot architecture and physical properties.

For example, the stiffness of the clot, fiber diameters, rate of fibrinolysis and interaction of coagulation factors with cells or the endothelium will be studied in varying conditions (e.g. modified fibrinogen, presence or absence of flow).

Secondary outcome

Not applicable.

Study description

Background summary

The clot structure is affected by different variables in the human body, for example modified forms of fibrinogen, glucose levels in the blood, activation of immune cells, activation of the endothelium or the presence of flow. Changes in the clot structure related to these variables can modify the risk of developing cardiovascular disease and might contribute to the bleeding phenotype of patients with a bleeding disorder.

Study objective

The aim of this fundamental research is to optimize methods and to investigate the effects of different variables in the human body on the clot structure, contributing to the knowledge of blood clotting, cardiovascular disease, and bleeding disorders.

Study design

Fundamental research.

Study burden and risks

A maximum of 20 ml blood is drawn from healthy volunteers at each collection, with a maximum of 5 times a year per donor. This is a low burden and minimal risks are associated with participation, since only blood is drawn.

Contacts

Public

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Voluntarily participation,
Between 18-70 of age,

Written informed consent

Exclusion criteria

Known disease that affects coagulation;
Treatment with medication that interferes with coagulation

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-09-2024

Enrollment: 30

Type: Anticipated

Ethics review

Approved WMO

Date: 04-10-2024

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL78124.078.21