

The Fear F8ctor Study

Published: 21-07-2015

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To explore the effects of acute fear on the coagulation system while sitting still.

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

Summary

ID

NL-OMON42572

Source

ToetsingOnline

Brief title

FF8 Study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Embolism and thrombosis

Synonym

blood clotting in vein (occlusion), Venous thrombosis

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Afdeling Klinische Epidemiologie;LUMC

Intervention

Keyword: Coagulation, fear, haemorrhagic diathesis, venous thrombosis

Outcome measures

Primary outcome

Individual markers of coagulation activity will be determined from the blood samples. Pulse rates will be measured analogously and an anxiety/fear score will be collected from each student for both movies. In addition, we will score (after the second movie) if students enjoy to watch fearful or dull movies, and if they have seen the presented movies before.

Secondary outcome

Not applicable.

Study description

Background summary

For centuries the term *blood curling* has been used to describe extreme frightening situations. The term dates back to the medieval physiology, it was believed that the human body contained four chief fluids, blood, phlegm, bile and black bile. It was thought that fear or horror would *run the blood cold* or *curdle* (solidify). To date large parts of the complex mechanism of the coagulation cascade have been unravelled and many risk factors for clotting, i.e., thrombosis have been identified. However, the origin of this ancient theory has never been studied and it remains unknown if fear induces the coagulation system.

Study objective

To explore the effects of acute fear on the coagulation system while sitting still.

Study design

In a crossover study design healthy subjects will be exposed to a horrifying e.g. scary movie followed by a dull e.g. flat movie which is shown at least 1 week after the first movie on the same day of the week at the same time of the day. One group will first see the scary movie, followed by the dull movie the

week after, the second group will see the movies in the opposite order.

Intervention:

Blood will be drawn from the cubital vein 10 minutes before the first movie, directly after the first movie. The same will be done 10 minutes before and directly after the second movie. Blood is drawn by using a needle puncture.

Study burden and risks

Blood is drawn 4 times via needle puncture of the cubital vein (12 ml per time point). Students will be offered free food and beverages directly after participation.

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

Participants will be recruited among students from the Leiden University Medical Center. All students must be between 18 and 30 years old, without any use of medication and otherwise healthy.

Exclusion criteria

Students will be excluded when they suffer from any kind of clinically identified coagulation disorder, anxiety disorder, use of hormonal contraception (excluding intra-uterine devices), in case of pregnancy or puerperium, when they have a history of venous thrombosis, had major surgery or cast-immobilisation of the lower extremity in the past two months or when they have a neoplasm or inflammatory disease.

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	29-07-2015
Enrollment:	26
Type:	Actual

Ethics review

Approved WMO	
Date:	21-07-2015

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL53805.058.15