Donation related stress and the effects on the donor*s haemostasis and the quality of the blood products.

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Assessing the effects of (anticipatory) stress associated with blood donation, by measuring basic psychological, physiological and hormonal parameters, on the donor*s haemostasis and the quality of the blood products.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON40894

Source
ToetsingOnline

Brief title
Donation induced stress effects (DISTRESS)

Condition

- Other condition

Synonym
strain, stress

Health condition

Stressreacties

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin Bloedbank
Source(s) of monetary or material Support: Sanquin eigen middelen

Intervention

Keyword: Blood donation, Blooddonor, Stress

Outcome measures

Primary outcome

The effects of stress on the donor*s haemostasis and the quality of the final

blood product will be examined (e.g. FVII, platelet activation).

Secondary outcome

Not applicable.

Study description

Background summary

Maintaining a constant supply of high-quality donor blood is essential for society. However, stress reactions, elicited by a blood donation, might have an effect on the final blood product. Therefore, insight is needed in the effects of psychological and physiological stress reactions on the donor*s haemostasis and the quality of the blood products.

Study objective

Assessing the effects of (anticipatory) stress associated with blood donation, by measuring basic psychological, physiological and hormonal parameters, on the donor*s haemostasis and the quality of the blood products.

Study design

Blood donors will be followed in the course of one blood donation. Psychological, physiological, and hormonal parameters will be measured at different points in the donation procedure. The effects of donation stress on the donor*s haemostasis and the quality of donated blood products will be

investigated.

Study burden and risks

All measurements will be incorporated in one routine blood donation. This avoids an extra visit to the blood bank and consequently decreases the burden on the donor.

Contacts

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Sanquin Bloedbank

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Sanquin Bloedbank

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Eligible to be or become a blood donor, according to the eligibility rules of Sanquin
- Whole-blood donor (at measurement)

- Sufficiently able to read and write Dutch

Exclusion criteria

- Use of aspirin in the previous week
- Use of beta-blockers
- Use of corticosteroids

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):	01-10-2014
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2014
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	NL48314.018.14