Kinetics of IroN in Donors

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

Summary

ID

NL-OMON35042

Source
ToetsingOnline

Brief title
KIND

Condition

- Other condition

Synonym
Iron status after blood donation; erythropoiese

Health condition

fysiologisch herstel na bloeddonatie in gezonde mannen

Research involving
Human

Sponsors and support

Primary sponsor: Sanquin Bloedbank
Source(s) of monetary or material Support: Sanquin bloedbank regio Zuid-oost

Intervention

Keyword: Blood donation, Iron depletion, Iron kinetics

Outcome measures

Primary outcome

Blood will be drawn 11 times in 8 weeks. DNA will be isolated and stored, and iron parameters measured. Furthermore, the participants will be asked to complete a shortened food frequency questionnaire specifically aimed at measuring iron intake, developed by the university of Wageningen.

The iron parameters included in this study are:

Hemoglobin (Hb)

Mean Corpuscular Volume (MCV)

soluble transferrin receptor (sTR)

Hepcidin

Iron

Transferrin

Reticulocytes and Reticulocyte Hb

Ferritin

C-Reactive Protein (CRP)

Zinc ProtoPorfyrin (ZPP)

Samples will be taken pre-donation, on the day of donation at 1, 2, 4 and 8 hours after donation and on days 2, 4, 8, 15, 29, 57 after donation. Not all parameters will be measured at all times. The timing of specific measurements

can be found in the protocol.

Secondary outcome

None

Study description

Background summary

Research on iron status of new donors and frequent donors has been done before. However, not much is known of the reaction of the human body to the loss of 500 mL of blood. How much does the iron content of the body decrease? What parameters related to erythropoiesis, iron status and iron metabolism change, and how do they change over time? Is the effect the same in new and frequent donors? How long does it take for the parameters to return to predonation levels?
In this study, we will measure the effects on the body of donation of 500 mL whole blood. The results will help evaluate whether time to next invitation should be diversified for various groups of donors. The knowledge might also be used in trauma patients.
However, before the study can be carried out in various groups of donors, it needs to be clear which parameters must be measured at what time after donation to characterize iron kinetics. There are no data in the literature. We will therefore carry out a pilot study among three donors, in which at multiple moments after donation blood will be drawn to analyse the parameters that characterize the iron kinetics. (absorption, distribution, metabolism and excretion, ADME).

Study objective

This pilot study will enable us to assess critical sample points in time to be able to draw a reliable curve of the concentration of various parameters that play a role in iron kinetics. This is essential for the planning of future research into the adaptation to blood donation in groups of donors.

Study design

This pilot study will be a longitudinal study with repeated measurements.

Study burden and risks

The burden to the participants of this study is moderately large. After

donation, they need to spend 8 hours on the Centre for Clinical Research where they will be given a catheter to facilitate blood sampling. This brings minimal risks for bleeding, infection and clots. In the days and weeks following donation another 6 sampling moments will follow. For these, the participants need to present at the blood bank. Again, a small risk of bleeding and infection is present.
The most frequent side effect of blood sampling is a hematoma in the elbowcrease.
The participants will lose more blood than usually at donation. However, as we will select tall healthy men, the total amount of blood taken does not exceed 13% of total blood volume. This is similar to the proportion of bloodvolume taken from smaller donors in regular donations.

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

Male, Donor since max 2 years, BMI between 20 and 27, length at least 175 cm, age between 30 and 60, ferritin at start between 120 and 250 microgram per litre, ALAT and CRP normal at start

Exclusion criteria

vegetarian, blood type O neg

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):	08-11-2011
Enrollment:	3
Type:	Actual

Ethics review

Approved WMO

Date:	07-12-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL31690.091.10