Kinetics of IroN in Donors

Published: 11-10-2012
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To assess the effect of whole blood donation on iron kinetics, iron absorption and iron incorporation into erythrocytes in new and frequent male whole blood donors.

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

Summary

ID

NL-OMON37151

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

Hb and red cell and reticulocyte indices (MCV, MCH, RDW, Ret Hb), serum iron parameters (iron, ferritin, transferrin, transferrin saturation, serum transferrin receptor (sTfR), zinc protoporphyrin (ZPP), hepcidin) and erythropoiesis marker (EPO).

Secondary outcome

Blood volume, number of previous donations, donation frequency

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.

Study objective

To assess the effect of whole blood donation on iron kinetics, iron absorption and iron incorporation into erythrocytes in new and frequent male whole blood donors.

Study design

Longitudinal design with 10 sample moments in 180 days.

Study burden and risks

Donors will lose 500 ml of blood with the donation and 235 ml at the sample moments. In total, this is 735 ml. This amount does not exceed 15% of total blood volume. The maximum proportion of blood acceptable for donation has been put at 15% of the total blood volume.29
At every sampling moment there is a minimal risk of bleeding and infection. The most frequent side effect of blood sampling is a haematoma in the elbow crease. The stable isotopes of iron 57Fe and 58Fe have been repeatedly used as a research tracer for iron bioavailability in population groups such as adults, pregnant women, children and infants and are safe for human consumption. The iron concentrations used in this study are within the iron concentrations expected from dietary iron intake and are a factor 10 lower than supplemental (pharmacological) iron dosages. No side effects for the stable iron isotopes are ever reported.

Contacts

Public
Sanquin Bloedbank

Geert Grooteplein Zuid 34
Nijmegen 6525 GA
NL
Scientific
Sanquin Bloedbank

Geert Grooteplein Zuid 34
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Male, 2 or less blood donations or 10 or more blood donations, BMI between 20 and 27, length at least 175 cm, age between 30 and 50, ALT and CRP normal at start

Exclusion criteria

vegetarian, blood type O neg, HFE mutation (homozygote C282Y or compound heterozygote C282Y/H63D genotype)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	11-10-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	14-04-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-03-2020
Application type:	Amendment
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	NL40948.091.12