Ferritin-guided iron supplementation in whole blood donors: Optimal dosage, donor Response and reTurn and Efficacy (FORTE) - a randomized controlled trial

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON54880

Source
ToetsingOnline

Brief title
FORTE

Condition

- Other condition

Synonym
Iron deficiency

Health condition

IJzergebrek (Ferritine)

Research involving

Human

Sponsors and support

Primary sponsor: Sanquin Bloedbank
Source(s) of monetary or material Support: Product and Process development Cellular Products (PPOC);Sanquin

Intervention

Keyword: Blood donation, Ferritin, Iron Supplementation

Outcome measures

Primary outcome

The primary outcome measure is the effect of iron supplementation on the iron

status (e.g. hemoglobin and ferritin) of the donors.

Secondary outcome

Secondary outcome measures are symptoms related to iron deficiency, general

health, donorship, compliance, lifestyle habits, side effects, and physical

activity.

Study description

Background summary

Rationale: Regular whole blood donors are at risk of developing iron deficiency due to the haemoglobin (Hb) -bound iron loss. Because plasma Hb levels do not accurately correspond with a donor's true iron status, Sanquin Blood Bank introduced ferritin measurements in whole blood donors as an indicator for iron depletion. Donation intervals are extended to 6 or 12 months for donors with ferritin levels of >=15 and <=30 µg/L or <15 µg/L, respectively. This policy lowers donor availability and may therefore cause a decrease in donations made over time, leading to an inadequate blood supply. Iron supplementation after blood donation has been shown to effectively enhance the recovery of Hb and ferritin levels, particularly in donors with low ferritin. Iron supplementation could serve as an alternative to the extended donation intervals. However, for the implementation of iron supplementation, more insights are needed regarding

the optimal supplementation protocol, effects on donation-related symptoms and health, and (non-)donors* and blood bank personnel*s knowledge and perception regarding iron deficiency and supplementation.

Study objective

The general aim of the FORTE study is to determine the optimal iron supplementation protocol in terms of dosage and frequency for blood donors with low ferritin levels. The results from this study will serve as evidence to support decision-making regarding iron supplementation policies as a measure to mitigate iron deficiency in blood donors.

Study design

3,000 donors with a planned ferritin measurement during their next whole blood donation will be asked to complete a questionnaire. 1200 whole blood donors with a ferritin levels <=30 µg / L will be randomly divided into 6 groups: low dose iron supplementation every other day, low dose iron supplementation every day, high dose iron supplementation every other day, high dose iron supplementation every day, placebo supplementation every day, daily placebo supplementation . The baseline visit consists of a standard blood donation, during the follow-up visits after 56 days, 122 days, and 6 months, a few tubes of blood are taken. The intervention period starts after the baseline visit and lasts until the first follow-up visit. Donors are asked to complete a questionnaire before, during, or shortly after each visit.

Intervention

56 days of supplementation with iron or placebo capsules:

- Every other day supplementation with low-dose iron capsules
- Daily supplementation with low-dose iron capsules
- Every other day supplementation with high * dosed iron capsules
- Daily supplementation with high * dosed iron capsules
- Every other day supplementation with placebo capsules
- Daily supplementation with placebo capsules

*to distinguish between the two iron doses, the higher dose has been described as "high". However, the actual iron dose is not a high dose when compared to iron supplements prescribed by a doctor in the case of iron deficiency.

Study burden and risks

Participation in the study has a negligible risk. In some cases, however, iron supplementation may lead to mild gastrointestinal discomfort.

Furthermore, the burden for the donors consists of 3 extra visits to the blood bank during a period of 6 months, collecting 3 additional blood samples, supplementation for 56 days with the provided capsules, and the completion of 4 questionnaires.

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

For the baseline questionnaire/measurement
-Whole blood donors should donate at one of the participating Sanquin locations.
-A ferritin measurement should be planned for their next donation.

For participation in the trial
-Successfully donated whole blood at baseline.

-Ferritin level should be <= 30 µg/L.

Exclusion criteria

-Donors who do not master the Dutch language.
-Donors who are currently or in the last 3 months supplemented with iron prescribed by their doctor can't participate in the trial.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-07-2021
Enrollment:	3000
Type:	Actual

Ethics review

Approved WMO

Date:	02-06-2021
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	NL73283.018.20
Other	NL8590