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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27514

Source
NTR

Brief title
FORTE

Health condition

Non-anaemic iron deficiency

Sponsors and support

Primary sponsor: Sanquin
Source(s) of monetary or material Support: Research Programming Committee Sanquin

Intervention

Outcome measures

Primary outcome

The primary outcome is the effects of four different iron supplementation protocols on ferritin

and Hb levels and donor health, to placebo in donors with low ferritin levels.

Secondary outcome

The secondary outcome includes the difference in effects between different iron supplementation protocols

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.
Objective: The primary objective is to investigate effects of iron supplementation on markers of body iron status, donor health including side effects, and iron deficiency-related symptoms, compared to placebo. For the secondary objective, the effect of different iron supplementation protocols (i.e. frequency and dose) are investigated.
Study design: Randomized controlled trial
Study population: The study population will consist of 2,400 Dutch whole blood donors who have previously donated at least once before participation in this study. Seemingly healthy donors with ferritin levels of ≤30 µg/L will be selected. Donors that do not master the Dutch language will be excluded.
The study population for the mixed methods study will consist of frequent donors, potential new donors, and Sanquin Blood Bank staff. The frequent donors must have donated at least 5 times and did not participate in the randomized controlled trial. Furthermore, all participants must be fluent in Dutch to be able to participate.
Intervention: Donors will be randomly divided into 1 of 6 groups: (I) alternate day placebo supplementation, (II) daily placebo supplementation, (III) alternate day low dose iron supplementation, (IV) daily low dose iron supplementation, (V) alternate day high dose iron supplementation, and (VI) daily high dose iron supplementation.
Main study parameters/endpoints: The main study endpoints are ferritin and hemoglobin levels.
Nature and extent of the burden and risks associated with participation, benefit, and group

relatedness: At baseline, participants will visit one of the co-operating Sanquin locations to donate blood. Here, blood will be collected from the sampling pouch. During follow up visits at 56 days, 122 days, and 6 months blood will be collected by venipuncture. Both baseline and follow-up visits will not introduce any further risk than an ordinary blood donation and participation may have beneficial effects for the participants receiving supplements by reducing symptoms related to iron deficiency. However, iron supplementation could cause gastrointestinal discomfort. Furthermore blood samples will be taken more often, and donors will need to invest time to complete questionnaires and for the additional visits to the blood bank.

Study objective

Post-donation iron supplementation will be an effective strategy to enhance the iron status recovery in whole blood donors with low ferritin levels.

Study design

Baseline (t=0), first follow-up visit (t=56 days), second follow-visit (t=122 days), final follow-up visit (t=6 months)

Intervention

Iron supplementation

Contacts

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Eligibility criteria

Inclusion criteria

- The donors must meet all the standard requirements to donate
- A ferritin measurement must be planned during the next donation
- The baseline donation must be succesful
- Ferritin level should be ≤ 30 µg/L

Exclusion criteria

- The donor does not master the Dutch language.
- The donor is currently or has in the last 3 months been taking iron supplements prescribed by their doctor.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2021
Enrollment:	2400
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
Study results are published in peer-reviewed journals after evaluation of scientific relevance and quality by the involved researchers. Furthermore, the results are presented at (inter)national conferences, shared with study participants, and communicated with donors

and different Sanquin departments. Data that can lead to the identification of the participants will not be published.

Ethics review

Positive opinion

Date:	07-05-2020
Application type:	First submission

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
NTR-new	NL8590
Other	METC AMC : T.B.A.

Study results

Summary results
2020_206