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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27514

Bron
Nationaal Trial Register

Verkorte titel
FORTE

Aandoening

Non-anaemic iron deficiency

Ondersteuning

Primaire sponsor: Sanquin
Overige ondersteuning: Research Programming Committee Sanquin

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Iron supplementation

Contactpersonen

Publiek

Sanquin
Jan Karregat

0650093376

Wetenschappelijk

Sanquin
Jan Karregat

0650093376

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen

(Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2021
Aantal proefpersonen:	2400
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
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.

Ethische beoordeling

Positief advies

Datum:	07-05-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8590
Ander register	METC AMC : T.B.A.

Resultaten

Samenvatting resultaten
2020_206