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Regulatory Criteria Sufficient to Preserve Red Cells Used for Transfusions, Including From Iron-Deficient Blood Donors

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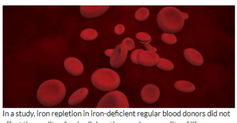

In a study, iron repletion in iron-deficient regular blood donors did not affect the quality of red cell donations or donor quality of life or cognition. *Source: Getty Images*

Research involving regular blood donors suggests that current regulatory criteria appear sufficient to preserve the quality of red cells used for transfusions. Additionally, quality of life (QOL) and cognition in donors appeared not to be affected by donation-induced iron deficiency or by iron repletion. The findings were published in the journal *Blood*.

Regular blood donors are at risk of iron deficiency related to donation-induced iron loss. However, the possible impact of this on the quality of red cell transfusions or on donor well-being have not been clear. In this study, the researchers aimed to evaluate effects on regular donors and the quality of donations from them.

The Donor Iron Deficiency Study (DIDS; ClinicalTrials.gov Identifier: NCT02889133) was conducted by researchers based at Columbia University and the New York Blood Center, both in New York City. This study included frequent blood donors, which involved 2 or more whole blood donations in the prior year for males and 1 or more donations in the prior year for females. Eligible participants had evidence of iron deficiency, with a ferritin level below 15 mg/L and a zinc protoporphyrin level greater than 60 mMol/mol heme.

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Participants were randomly assigned 1:1 to receive either iron repletion (intravenous 1 g low molecular-weight iron dextran) or a saline placebo. Participants donated blood twice during the study, with the first donation being prior to treatment and the second being 5 months later, after treatment. Both donations were evaluated for red cell storage quality through a 51-chromium posttransfusion red cell recovery study.

The primary study outcome was the change in posttransfusion recovery on a within-subject basis, and participants were also evaluated for multiple QOL measures and for cognitive function. Cognitive function results were obtained from an ancillary study (ClinicalTrials.gov Identifier: NCT02990559).

The study included 79 eligible donors who were iron deficient, with 39 randomly assigned to the iron-repletion arm and 40 to the placebo arm. Analyses of donations from prior to treatment showed that all had achieved US Food and Drug Administration criteria for posttransfusion recovery.

Iron repletion appeared not to have an impact on the primary outcome of posttransfusion recovery. With iron repletion, the mean change in posttransfusion recovery was 1.6% (95% CI, -0.5 to 3.8), and without iron repletion, the mean change was -0.4% (95% CI, -2.0 to 1.2), which reflected a nonsignificant difference between groups. Among prespecified subgroups, female donors showed a significantly higher posttransfusion recovery following iron repletion, compared with the placebo (P <.05).

With measures of well-being or cognition, there were not effects observed between iron-repletion and placebo arms. Also, although blood donations led to anemia in many patients, donations themselves appeared not to be associated with QOL or cognitive outcomes.

"In conclusion, the DIDS trial found that current regulatory criteria for blood donation maintain red cell storage quality for transfusion without exposing adult donors to measurable adverse effects on quality of life or cognition resulting from blood donation-induced iron deficiency," the investigators wrote in their report.

Reference

Hod EA, Brittenham GM, Bitan ZC, et al. A randomized trial of blood donor iron repletion on red cell quality for transfusion and donor cognition and well-being. *Blood*. 2022;140(25):2730-2739. doi:10.1182/blood.2022017288

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