

Donor iron deficiency found to have no harmful effects on blood quality or donor well-being

September 7 2022



Change in red blood cell post-transfusion recovery between randomization arms and by pre-specified subgroups. Bars represent mean change in red blood cell post-transfusion recovery between the second measure performed after



randomization and the first measure before randomization to placebo (open blue circles) or iron repletion (open red triangles). (A) Overall change in post-transfusion recovery among all randomized participants completing the primary outcome measure and by (B) sex, (C) age, and (D) race. Error bars represent standard deviation. *P Blood (2022). DOI: 10.1182/blood.2022017288

Most of the U.S. blood supply comes from about 5 million altruistic volunteers who donate blood regularly. Frequent blood donation is known to result in iron deficiency in donors, which has led to concerns that the practice may not only diminish the quality of donated blood but also harm blood donors' health and quality of life. Reassuringly, a new study published in *Blood* found that donor iron deficiency produced no harmful effects on either the quality of donated blood or the well-being of frequent blood donors.

Red blood cells require <u>iron</u>, an essential dietary element, to transport oxygen throughout the body. Iron deficiency may lead to anemia (a shortage of <u>red blood cells</u>) and associated symptoms, including fatigue, depression, and brain fog. Although a 2012 study found that roughly 35% of regular <u>blood donors</u> become iron deficient after repeated blood donations, few studies have evaluated the effects on <u>donor</u> health or on the quality of donated blood.

"The results of our study offer robust evidence that the existing criteria for <u>blood donation</u> both preserve the quality of the blood supply and protect the well-being of adults who are frequent blood donors," said Eldad A. Hod, MD, an associate professor of pathology and <u>cell biology</u> at Columbia University's Irving Medical Center in New York, and the study's first author.

Dr. Hod added that he hoped the study's findings encourage more people



to become blood donors. According to a 2019 study, less than 6% of people over 18 years old in the United States had given blood within the previous year. An increase in the number of donors would improve the blood supply and reduce reliance on those who donate frequently, he said. The COVID-19 pandemic has exacerbated an existing shortage of donated blood in the United States, leading to delays in planned blood transfusions and cancelations of surgery due to a lack of blood products.

The Donor Iron Deficiency Study screened 983 frequent blood donors ages 18 to 75. Of the 110 iron deficient, but non-anemic, donors, 79 were ultimately randomized. Donors who were too anemic to donate blood, pregnant, or had conditions that put them at risk for anaphylactic shock with iron treatment (e.g., severe allergies) were excluded.

Following screening to confirm their eligibility, all participants donated one standard unit of blood. These donors also completed questionnaires about their physical and mental health and <u>quality of life</u>, and completed tests of their cognitive ability, including memory, attentiveness, and ability to process information.

Participants returned about six weeks later to complete quality of life and cognitive testing again, together with a test to determine whether the blood they had donated on their previous visit met the U.S. Food and Drug Administration's (FDA's) quality standard for donated blood. After completing these tests, they were randomly assigned to receive an intravenous infusion of either iron or a placebo substance (saline solution). The study was double blinded, meaning that neither the participants nor members of the study team knew who had received the iron infusion and who had received the placebo.

Four to six months later, participants returned to make a second blood donation and complete another round of quality of life and cognitive testing. Six weeks after this second donation, they undertook a second



test to determine whether the quality of this donated blood met the FDA standard and then completed a final assessment of quality of life and cognition. The primary endpoint of the study was the change in participants' results on the first blood-quality test when all donors had low iron levels, and the second test, performed after the donors had been randomly assigned to receive treatment with intravenous iron or a placebo.

While Dr. Hod and colleagues predicted that donated blood would fail to meet the FDA's quality standard and that donors' well-being would improve with additional iron, the study's results defied expectations. Among those who were randomly assigned to receive intravenous iron, the treatment corrected their iron deficiency, while participants who received the placebo remained iron deficient, with many developing anemia. Nevertheless, the donated blood from the iron-deficient donors who received a placebo still met the FDA's quality standards, and their scores on both cognitive function tests and quality-of-life measures showed no significant differences at any time point from those of the donors whose iron deficiency had been corrected with intravenous iron.

"This finding is good news because it not only shows that blood donated by frequent donors remains of high quality, but also that those who donate blood regularly are not being significantly harmed by doing so," explained Dr. Hod.

One limitation of the study's findings is that people under age 18 were excluded from participation. About 10% of all <u>blood</u> donors are in this age group, according to Dr. Hod. Adolescents need iron for brain development, a process that isn't complete until they reach their mid-20s, he said. "We don't know to what extent our results can be generalized to the under-18 population," he said. "We hope to look at this age group in our next study."



More information: Eldad A Hod et al, A randomized trial of blood donor iron repletion on red cell quality for transfusion and donor cognition and wellbeing, *Blood* (2022). <u>DOI: 10.1182/blood.2022017288</u>

Provided by American Society of Hematology

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