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POSTER ABSTRACTS

401.BLOOD TRANSFUSION

Impact of Iron Supplementation in Anemic Voluntary First-Time Blood Donors-Results of a Pilot Trial in Ghana

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Introduction: Blood transfusion is a major developmental challenge in sub-Saharan Africa due to chronic inadequacy and shortage of major blood products. In Ghana, deferral of potential blood donors has been identified as a significant challenge. Anemia, accounts for nearly half of ineligible blood donors. The estimated prevalence of anemia is 42.4% in women of reproductive age and 18.8% among peri-urban men (*Spring and Ghana Health service 2016*). Thus, a high prevalence of anemia accounting for nearly half of voluntary blood donor deferrals, may contribute to the country's poor availability of safe blood for transfusion. No prior investigation had been carried out in Ghana on whether potential blood donors, deferred due to anemia, would consider donating blood after receiving counselling and appropriate treatment. This study tested the hypothesis that low-dose iron supplementation will increase hemoglobin levels sufficiently among anemic individuals to make them eligible to donate blood. Data from this trial informed the design of a larger randomized control type 1 pragmatic effectiveness implementation hybrid trial.

Methods:This was a longitudinal two-arm parallel-group trial (participants aged 18 - 60 years). We compared the hemoglobin levels among those with anemia, iron deficiency (ID) or iron deficiency anemia (IDA) who received iron supplementation to donors without ID or IDA (Control group) in a non-inferiority design(NCT04949165). Anemia, IDA and ID were defined and determined using World Health Organization cut-off values (*WHO*, 2011). Potential blood donors with hemoglobin values less than 10 g/dl were excluded from the study. Participants in the iron supplementation arm were given low-dose iron (65 mg elemental iron) three times weekly for four months while the control arm received the standard nutritional counselling practice. In-person visits occurred at two, four and six months and included blood draws for full blood count, peripheral blood film smear, malaria rapid test and serum ferritin. The primary outcome was hemoglobin level after four months. A structured questionnaire assessed adherence, nutritional counselling and adverse events every two weeks via phone.

Results: Two hundred and twenty-three first-time voluntary blood donors consented and passed pre-screening donation requirements (105 in iron supplementation arm vs. 118 in the control arm). The mean ages were similar between the iron supplementation and control groups (19.7 ± 2.5 vs. 20.1 ± 3.1 years). In both groups, there were more females than males (iron: 75.2%; control: 51.7%). At screening, 43.9% (98/223) had anemia while 3.1% (7/223) had ID. Of those who had anemia, 84.7% (83/98) had ferritin at least 15 g/l while 15.3% (15/98) had IDA. Among controls who donated blood at screening with an interim 1 visit, 42.6% (20/47) of females and 20.9% (9/43) of males were anemic. Only 23.4% (11/47) of females but no male was ID after one blood donation. Among participants assigned to iron supplementation who were anemic at screening, 31.7%

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(20/63) of females and 28.6% (6/21) of males were no longer anemic at interim visit 1. Among iron participants who were ID at screening 53.3% (8/15) of females and no male (0/2) were iron replete at interim visit 1. Only half of the participants receiving iron supplementation self-reported perfect adherence at the first and second interim visits (end of iron supplementation). A small proportion of participants reported side effects of dark stools and abdominal pain. We did not observe bacterial infections or increased malaria incidence. The mean hemoglobin values decreased over time from baseline to month four in the control group (screening: N=118, 13.4 \pm 1.3 g/dl; interim visit 2: N=74, 12.3 \pm 1.5 g/dl) and increased in the iron supplementation group (screening: N=105, 11.3 \pm 0.9 g/dl; interim visit 2: N=56, 11.4 \pm 1.3 g/dl). However, the primary comparison, mean hemoglobin difference between the iron supplementation and control arm at four months, did not meet the threshold to reject the inferiority hypothesis.

Conclusion: The prevalence of ID and IDA among voluntary first-time blood donors was lower than previously published estimates. Adherence to low-dose iron supplementation three times a week was poor. Hemoglobin levels in the iron supplementation arm were not close enough to those in the control group after four months of iron supplementation to declare non-inferiority.

Disclosures No relevant conflicts of interest to declare.

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