Randomized Controlled Trial

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**Impact of weekly iron folic acid supplementation with and without vitamin B12 on anaemic adolescent girls: a randomised clinical trial**

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**Abstract**

**Background/objectives:**In India, approx. 70% of the adolescent girls are anaemic (haemolgobin <120 g/l). The present study was a supervised randomised double-blind clinical trial conducted among adolescent girls (11-18 years) to assess and compare the impact of weekly iron folic acid (IFA) supplementation with or without vitamin B12 on reduction in the prevalence of anaemia and on blood/serum levels of haemoglobin, serum ferritin, folic acid and vitamin B12.

**Subjects/methods:**Community-based randomized controlled trial was carried out in Kirti Nagar slums of West Delhi. A total of 446 mild (100-119 g/l) and moderate (70-99 g/l) anaemic volunteer adolescent girls were identified and randomised into two groups. Weekly supervised supplementation was given for 26 weeks: Group A (n=222): iron (100 mg), folic acid (500 mcg) and placebo; Group B (n=224): iron (100 mg), folic acid (500 mcg) and cyanocobalamin (500 mcg for 6 weeks and 15 mcg for 20 weeks). Haemoglobin, serum ferritin, folic acid and vitamin B12 levels were assessed at baseline and after intervention. A total of 373 subjects completed 26 weeks of supplementation successfully.

**Results:**The mean haemoglobin increased from 106.7±11.2 g/l and 108.9±8.91 g/l in Group A and Group B at baseline to 116.4±10.8 g/l (P<0.001) and 116.5±10.26 g/l (P<0.001) at post-intervention, respectively, with the reduction in the prevalence of anaemia by 35.9% in Group A and 39.7% in Group B (P>0.05). A total of 63.3% participants had deficient vitamin B12 levels (<203 pg/ml) at baseline, which reduced to 40.4% after intervention with cyanocobalamin, whereas no change was observed in vitamin B12 status in the other group. Significant reduction (P=0.01) in the prevalence of serum ferritin deficiency (<15 ng/ml) was observed in the group supplemented with vitamin B12 (from 36.5 to 6.4%) as compared with the other group supplemented with only IFA (from 39.1 to 15.2%).

**Conclusions:**IFA supplementation with or without vitamin B12 is an effective measure to cure anaemia. Although addition of vitamin B12 had similar impact on improving haemoglobin status as IFA alone, it resulted in better ferritin status. Hence, more multi-centre studies with a longer duration of supplementation or higher dose of vitamin B12 may be undertaken to assess the possible impact of vitamin B12 on improving haemoglobin levels in the population.