

## **6. ABSTRACT**

**Iron deficiency anaemia in pregnancy and weekly versus daily antenatal oral iron and folic acid supplementation in non anaemic pregnant women: a randomized controlled trial.**

### **Introduction**

The prevalence of anaemia in pregnancy at present is estimated to be < 20% in Sri Lanka. Therefore weekly oral iron supplements could be adequate and daily supplements may be unnecessary for non anaemic pregnant women in Sri Lanka.

### **Objectives**

To determine the rate of anaemia and iron deficiency (ID ) in women presenting for antenatal care, to evaluate the agreement between their hemoglobin concentrations (Hb) and hematocrit (Hct) obtained from two different laboratories and to evaluate the effectiveness of weekly versus daily antenatal oral iron and folic acid supplementation in non anaemic pregnant women, in preventing anaemia and ID.

### **Method**

Consecutive pregnant women (n = 350) between 12 to 20 weeks of gestation, presenting for antenatal care had their Hb and Hct measured at Academic Obstetric Unit at Teaching Hospital Mahamodera, Galle, (THMG) by an Auto Hematology Analyzer, using colorimetry and flow-cytometry, and hydro-dynamic focusing methods at Durdans Hospital Laboratory Galle (DHLG). Serum ferritin (SF) was measured using electrochemiluminescence at the DHLG. Rates of anemia and ID were calculated and the agreement of the results of the two laboratories was evaluated.

The non anaemic pregnant women (n=291) between 14 to 22 weeks gestation, were randomly allocated to receive 120 mg elemental iron and 3 mg of folic acid weekly (n=149) or 60 mg of elemental iron and 1 mg folic acid daily



(n=142). All subjects were assessed for compliance and side effects at four weekly intervals and their Hb, Hct and SF were measured at 32 to 36 weeks of gestation.

## Results

The rate of anemia was 16.6%. The best cut off level of SF for the prediction of anemia was SF < 30 µg/L (the area under the ROC curve was 0.77 with 95% CI -0.72 to 0.81), and it had a sensitivity of 78.3% (95% CI 65.8 - 87.9) and a specificity of 74% (95% CI 68.6 – 79.0) in predicting anemia. Using this SF < 30 µg/L cut off, 36.9% of subjects had ID.

The mean Hb of the participants, obtained from both laboratories, was 11.6 (95% CI 11.4 – 11.7). The mean Hct too was similar (33.8%, 95 % CI 33.3 – 34.2 in DHL Laboratory vs. 34%, 95% CI 33.6 – 34.5 in THMG Laboratory. The limits of agreement and the clinical limits of indifference between the Hb and Hct values obtained from the two laboratories were good with individual differences of > 10% being seen in < 5% of results.

At the commencement of the randomized control trial there were no significant differences in monthly family income, educational level, age, parity, pre supplementation Hb, Hct and SF, and duration of previous haematinic prophylaxis between the two groups. Only 106 (74%) in the daily supplementation group and 106 (72%) in the weekly supplementation group completed the study. There were no significant differences in the mean duration of supplementation, during the study, between the two groups. Using the results from the DHL Laboratory there were no significant differences in the pre and post supplementation mean Hb, Hct and SF, or the risks of developing anaemia or ID between the two groups. However, there was a significant reduction in the SF levels at 32-36 weeks. The side effects were significantly greater in the daily supplementation group compared to the weekly supplementation group.

## Conclusion

Anaemia (16.6%) and ID (36.9%) are apparently of mild to moderate public health significance respectively, in women presenting for antenatal care. There was good agreement between the hematological reports obtained from two laboratories. In non anaemic pregnant women daily antenatal oral iron supplements are not superior to weekly oral iron supplements in preventing anemia and ID in the third trimester.