

# Efficacy of Sideral® Folic supplementation in pregnancy: a feasibility study

Sena T. <sup>1</sup>, Carillo C. <sup>2</sup>, Moretti S <sup>3</sup>, Rossato MS <sup>4</sup>, Tarantino G<sup>4\*</sup>, Munoz M<sup>5</sup>.

1. Reproduction Medicine Unit ASL NA 1, Naples (Italy) - 2. Department of Gynecology and Obstetrics, S. Eugenio Hospital, Roma, Italy - 3. G. B. Grassi Hospital, Roma, Italy – 4. Pharmanutra Spa – 5. Department of Surgical Specialties, Biochemistry and Immunology, School of Medicine, University of Málaga, Málaga (Spain); \*corresponding author

## BACKGROUND

Iron deficiency (ID) and iron deficiency anemia (IDA) affect about 20% of pregnant women in the Western world, rising to 56% in developing countries. 80% of not iron supplemented women with full-term pregnancy have no detectable iron deposits.

## METHODS

Multicenter, prospective observational study of pregnant women receiving **Sideral® Folic** (Pharmanutra Spa, Italy), **Sucrosomial® Iron, 30 mg** of elemental iron; Vitamin C, 70 mg; Folic acid, 400 mg; Vitamin B6, 1 mg; Vitamin B12, 1.75 mg; Vitamin D, 10 mg, daily from the first check-up to delivery. Both spontaneous (SP) and medically assisted pregnancies (MAP) were included.

**Inclusion Criteria:** women aged 18-45 presenting with confirmed pregnancy and Hb ≥ 11 g/dL at first screening (non-anemic or mildly anemic).

**Exclusion Criteria:** Pathologic pregnancy, gestational diabetes, pre-eclampsia, microcytosis; BMI < 18 or > 32 at early pregnancy Hb < 9.5 g/dL at any time during pregnancy.

## RESULT

A total of **41 women** (mean age of 33 years; 16 MAP and 25 SP) completed the study. Average delivery was at week 39, though two twin pregnancies in the MAP group ended at week 34. Average newborn weight was 3230g in singleton pregnancies, and 2075g in twin pregnancies. The time-course of Hb is reported in **Table 1**.

Hb g/dL mean ± SD (n)	Conception	Start pregnancy	Week 5-7	Week 18-22	Week 27-32	Week 35-37	48 hours Postpartum
<b>ALL</b>	---	---	12.4 ± 0.9 (41)	12.0 ± 0.4 (35)	11.8 ± 0.7 (39)	12.1 ± 0.9 (33)	11.7 ± 1.0 (21)
<b>MAP</b>	12.5 ± 0.9 (16)	11.9 ± 0.4 (16)	11.9 ± 0.8 (16)	12.0 ± 0.5 (16)	12.0 ± 0.2 (16)	12.2 ± 0.4 (14)	11.8 ± 0.9 (15)
<b>SP</b>	---	---	12.7 ± 0.9 (25)	12.0 ± 1.1 (19)	11.7 ± 0.9 (23)	12.0 ± 1.1 (19)	11.8 ± 1.4 (6)

**Only 3 out of the remaining 35 women (8.6%) gave birth with an Hb value < 11 g/dL. The mean peripartum Hb loss was 0.4 g/dL. No women presented microcytosis or needed IV iron infusions.** The assessment of women's well-being showed that all symptoms progressively improved during pregnancy (**Figure 1**). Sideral® Folic supplementation allowed to maintain the Hb level, **avoiding RBC transfusions during pregnancy or after delivery in all the supplemented women.**

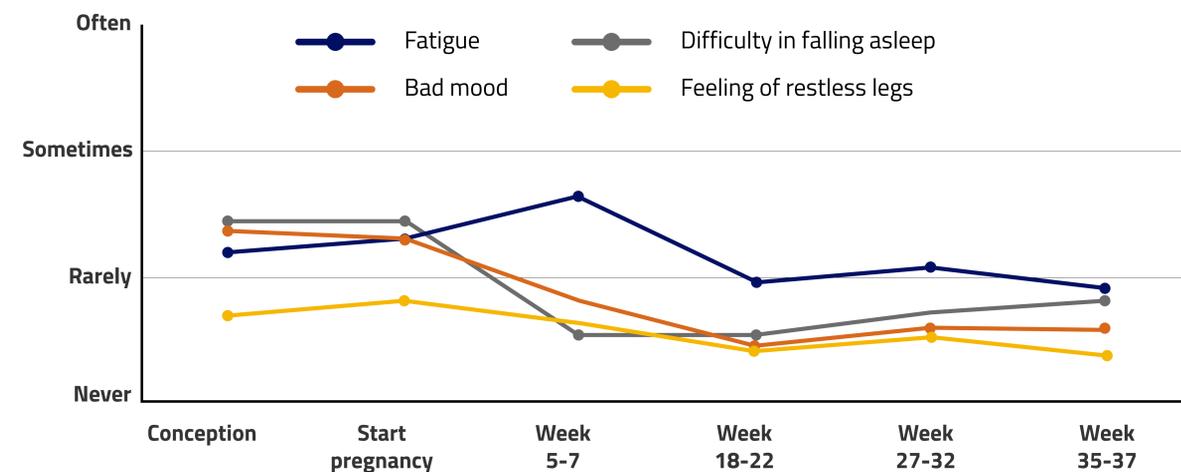


Figure 1. Well-being indexes

## CONCLUSIONS

**Daily iron prophylaxis with Sideral® Folic prevents ID and Hb decrease during pregnancy,** leading women to reach childbirth in a good state of wellbeing. Available postpartum Hb data showed that peripartum Hb loss was mild, thus reducing the risk to blood transfusion recurrency.