

In iron deficiency anemia and lactating mothers...



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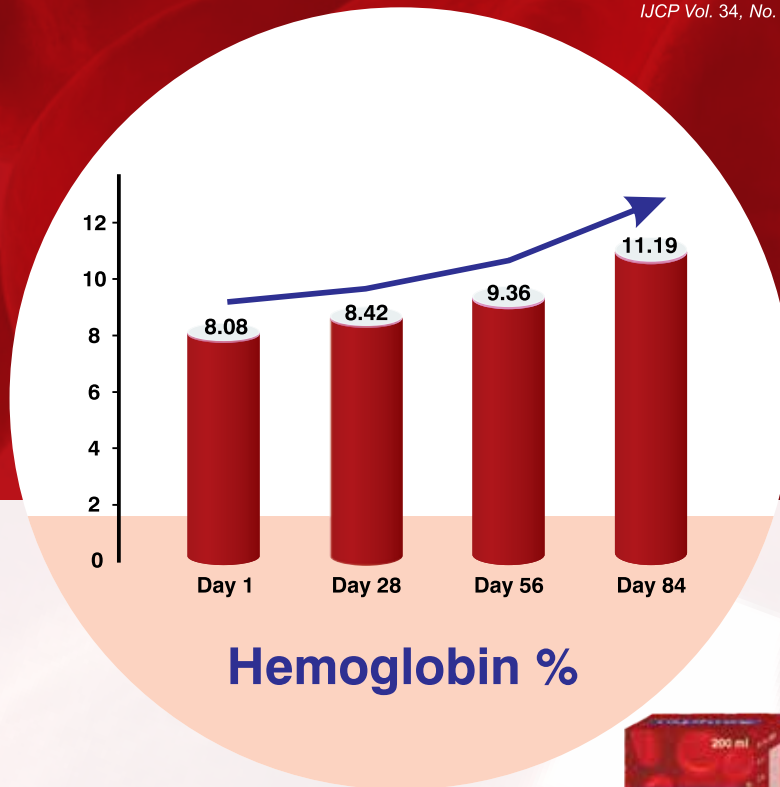
Sangfer

Liquid / Capsules

The haematinic with a difference

Significant rise in hemoglobin levels

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Hemoglobin %

Dosage:

Liquid: 10 ml 2 times a day

Capsules: 1 capsule 2 times a day



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Clinical Evaluation of an Ayurvedic Preparation “Sangfer” for the Treatment of Anemia in Pregnant Women: An Open-labeled Clinical Study

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ABSTRACT

Background: Iron deficiency during pregnancy is one of the primary causes of anemia in infants and young children. It has a negative impact on maternal and fetal health throughout pregnancy with higher likelihood of adverse maternal and fetal outcomes. Maternal iron supplementation is a critical tool to address the global problem of iron deficiency and prevent its negative consequences. **Method:** An open-label non-comparative prospective clinical trial was carried out to evaluate the effectiveness of “Sangfer” liquid in 16 pregnant women with anemia. “Sangfer” is a polyherbal Ayurvedic proprietary medication containing elemental iron and zinc and four medicinal herbs viz. *Withania somnifera*, *Embllica officinalis*, *Asparagus racemosus* and *Pueraria tuberosa*. The aim of the study was to examine its efficacy and safety in treating anemia in pregnant women. The dose administered was 10 mL twice daily after food for 12 weeks (84 days). Patients were evaluated at screening (Visit 1 at Day 0), baseline (Visit 2 at Day 1) and during follow-ups (Visit 3 at Day 28, Visit 4 at Day 56 and Visit 5 at Day 84). **Results:** There was a significant increase in mean hemoglobin levels from 8.08% at Day 1 to 11.19% at the final visit at Day 84. The anemia sign and symptom scores also significantly reduced from Day 1 to different follow-up visits. The mean Physician Global Assessment (PGA) score was found to reduce from 1.0 at Day 1 to 0.0 at the final follow-up visit. **Conclusion:** “Sangfer” is highly effective for the treatment of anemia during pregnancy. No adverse effects including serious adverse effects were observed during the study period.

Keywords: Iron deficiency anemia, pregnancy, liquid, medicinal herbs, hemoglobin, anemia sign and symptom scores

Iron deficiency anemia (IDA) is very common, particularly in underdeveloped countries, and is now reaching a state of pandemic.¹ Iron deficiency during pregnancy is one of the primary causes of anemia in infants and young children.² Pregnancy increases iron demand, which increases the risk of anemia. It has a negative impact on maternal and fetal health throughout pregnancy, and has been associated with higher morbidity and fetal mortality.³ Breathing difficulties, fainting, fatigue, palpitations and sleep problems are common among affected mothers.⁴ They are also more likely to

have perinatal infection, pre-eclampsia and bleeding. There are also concerns of postpartum cognitive decline and behavioral difficulties.^{5,6} Anemia during pregnancy is also associated with poor perinatal outcomes such as preterm labor, intrauterine growth retardation, low birth weight, birth asphyxia and neonatal anemia.^{7,8} Maternal iron supplementation is a critical tool to address the global problem of iron deficiency and prevent its negative consequences.⁹ Since ancient times, numerous iron formulations have been empirically used in the treatment of anemia in Ayurveda.¹⁰

In this study, an Ayurvedic proprietary medication “Sangfer” containing elemental iron and zinc and four medicinal herbs *Withania somnifera*, *Embllica officinalis*, *Asparagus racemosus* and *Pueraria tuberosa* was investigated for its efficacy in the treatment of anemia in pregnant women.

Therefore, an open-label non-comparative prospective clinical trial was carried out to assess the effectiveness of “Sangfer” liquid in pregnant female participants with anemia.

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CLINICAL STUDY

STUDY OBJECTIVES

Primary Objective

The primary objective of this study was to evaluate the efficacy of “Sangfer” liquid in anemia in pregnant women.

Secondary Objective

The secondary objective was to assess the tolerability of the supplement in study participants.

STUDY DESIGN

This study was an open-label, single-arm, non-comparative prospective clinical study to evaluate the efficacy and tolerability of “Sangfer” liquid in pregnant women suffering from anemia. The 84-day study duration consisted of five assessment points, including screening (Visit 1, Day 0), baseline (Visit 2, Day 1), two follow-ups (Visits 3 and 4, Days 28 and 56, respectively) and final visit (Visit 5, Day 84). After receiving informed consent, subjects were evaluated for eligibility based on inclusion and exclusion criteria.

After baseline assessment at Visit 2, “Sangfer” liquid was given to all eligible subjects. Subjects were instructed to take the liquid 10 mL twice daily after food for 84 days (12 weeks).

STUDY POPULATION

Pregnant women with anemia were recruited from the outpatient clinic. Potential subjects were identified by the site investigator or by designated physician based on the inclusion and exclusion criteria. A total of 16 subjects were recruited for this study.

Inclusion Criteria

Subjects who met all of the following criteria were included in the study:

- Pregnant women aged between 18 to 35 years.
- Subjects up to the 7th month of pregnancy with a clinical diagnosis and laboratory confirmation of anemia, but with hemoglobin level not <8 g/dL.
- Subjects with hemoglobin level ≤ 10 g/dL and peripheral blood imaging showed microcytic, normocytic and hypochromic red blood cells.
- Subjects who were able to understand the risks/benefits of the protocol.
- Subjects who gave their written informed consent and agreed to come for regular follow-up.

Exclusion Criteria

Subjects who met any of the following criteria were excluded from the study:

- Participants with hemoglobin level ≤ 8 g/dL.
- Participants with a history of anemia due to any bleeding condition such as bleeding hemorrhoids, menorrhagia (cyclical vaginal bleeding excessive in quantity or duration), gastric ulcers, etc.
- Individuals with bleeding disorders such as coagulation defects, thalassemia, etc.
- Presence of any other comorbid disease such as renal failure, coronary disease, hypertension, tuberculosis, diabetes mellitus, etc.
- Subjects with history of thyroid dysfunction.
- History of psychiatric disorder that could affect subjects' ability to give written informed consent.
- Subjects with a history of stroke, myocardial infarction, coronary artery disease, heart failure, angina, life-threatening arrhythmia in the past 6 months.
- Subjects with uncontrolled diabetes (fasting blood sugar >140 mg/dL) and high blood pressure >130/90 mmHg.
- Subject with acquired immunodeficiency syndrome (AIDS) or history of any other sexually transmitted diseases (STDs).
- Subjects with high alcohol consumption (>2 standard drinks per day), smokers and recreational drug use (such as cocaine, methamphetamine, marijuana, etc.)/nicotine/caffeine dependence.
- Subjects who had participated in a clinical study in the last 30 days prior to entering this study.

STUDY PRODUCT DETAILS

The study product “Sangfer” is a proprietary Ayurvedic oral liquid for the treatment of anemia in pregnant women. “Sangfer” liquid contains medicinal plants (*W. somnifera*, *E. officinalis*, *A. racemosus* and *P. tuberosa*) used in Ayurvedic medicines.

CONCOMITANT THERAPY

No concomitant medication was allowed during the study. However, if participants reported any clinical symptoms during the study, the study physician prescribed the appropriate medication, which was documented.

STUDY ENDPOINTS

Primary Endpoint

- The primary endpoint included the mean change in hemoglobin level from baseline to the end of the study.

Secondary Endpoints

The secondary endpoints were included:

- Mean change in the global assessment on overall improvement by the investigator and by the patient from baseline to the end of the study.
- Change in subjective scores in the improvement of weakness (*Daurbalya*), fatigue (*Shrama*), breathlessness (*Shwasa*), pallor – skin, face, sclera, nails (*Pandu Varna Twak*, etc.) from baseline to the end of the study.
- Mean changes in vital sign parameters from baseline to end of study.
- Frequency and severity of the occurrence of adverse events during the treatment period.
- Proportion of subjects who discontinued study treatment due to adverse events.

STUDY ASSESSMENTS

Visit 1 (Screening): Screening events were performed at Visit 1 (Day 0). Potential subjects were identified and written informed consent was obtained from all participants. Eligible subjects meeting the entry criteria were enrolled in the study. All subjects were assessed for physical examinations, vital signs, demographic data, medical histories, including concomitant medications.

Visit 2 (Baseline): Baseline data was evaluated at Visit 2 (Day 1). During this visit, all subjects underwent physical examination, vital signs, concomitant medications, blood test for hemoglobin level, anemia sign and symptoms (weakness, fatigue, breathlessness and pallor) scores and Physician Global Assessment (PGA) score.

Visit 3 (Follow-up): All participants underwent a medical assessment during Visit 3. At this visit, all subjects were assessed for the physical examination, vital signs, concomitant medications, adverse events, blood test for hemoglobin level, IDA sign and symptoms scores and PGA score.

Visit 4 (Follow-up): All participants underwent a medical assessment during this visit (Day 56). They

underwent physical examination and were assessed for vital signs, concomitant medications, adverse events, blood test for hemoglobin level, IDA sign and symptoms scores and PGA score.

Visit 5 (End of the Study): All participants underwent a medical assessment during this visit (Day 84). At this visit, physical examination and assessment of vital signs, concomitant medications, adverse events, blood test for hemoglobin level, IDA sign and symptoms scores and PGA score were done.

STATISTICAL PLANS

Data were abstracted and presented as number, percentage, mean and standard deviation (SD). All efficacy and safety variables were summarized using descriptive statistics. Data comparison between baseline and follow-up visits was performed using paired *t*-test or one-way analysis of variance (ANOVA), as appropriate, and data were expressed as mean, SD, 95% confidence interval (CI) and *p*-value. A *p* value of 0.05 was considered statistically significant. Statistical analysis was done using statistical software SPSS 10.0.

RESULTS

Data Sets Analyzed

A total of 18 female subjects were screened for eligibility; 16 subjects enrolled in the study and 2 subjects were screening failures. All subjects were given the test product “Sangfer” liquid and instructed to take 10 mL liquid twice daily after meal for 84 days. All 16 subjects completed the study, and hence, the data of 16 subjects was analyzed for this study.

Demographic Data

The mean age of the participants was 23.94 ± 2.93 years. The maximum age enrolled was 31 years, and the minimum age enrolled was 20 years. The mean weight of the participants was 47.75 ± 2.89 kg.

Efficacy Assessment

Assessment of hemoglobin level

Hemoglobin levels were evaluated at Day 1 (V2) through Days 28 (V3), 56 (V4) and 84 (V5) (Table 1). Results showed a significant increase in the mean hemoglobin levels from Day 0 to different follow-up visits. Mean changes in hemoglobin levels on Days 56 and 84 were found to be statistically significant ($p < 0.0001$) compared to Day 1 (Table 2 and Fig. 1).

CLINICAL STUDY

Table 1. Mean Hemoglobin Level at Different Visits

Parameters	Visit (V)	Mean (n = 16)	SD
Hemoglobin (g/dL)	Baseline (V2, Day 1)	8.08	0.39
	Follow-up (V3, Day 28)	8.42	0.39
	Follow-up (V4, Day 56)	9.36	0.55
	Final visit (V5, Day 84)	11.19	0.67

Table 2. Comparison of Mean Change in Hemoglobin Level from Day 0 to Different Follow-up Visits

Parameters	Visit (V)	Mean score (mean \pm SD)	Change from V1 (mean \pm SD)	95% CI of Diff.	P value
Hemoglobin (g/dL)	V2	8.08 \pm 0.39	-	-	<0.0001
	V3	8.42 \pm 0.39	0.34 \pm 0.20	-0.8414 to 0.1539	
	V4	9.36 \pm 0.55	1.29 \pm 0.51***	-1.785 to -0.7898	
	V5	11.19 \pm 0.67	3.11 \pm 0.66***	-3.610 to -2.615	

Mean hemoglobin at Day 1 (V2) was compared with Days 28 (V3), 56 (V4) and 84 (V5) by one-way ANOVA test. Comparison: V2 vs. V3, V4 and V5. Level of significance ***p < 0.0001.

*P < 0.05, **P < 0.01, ***P < 0.001.

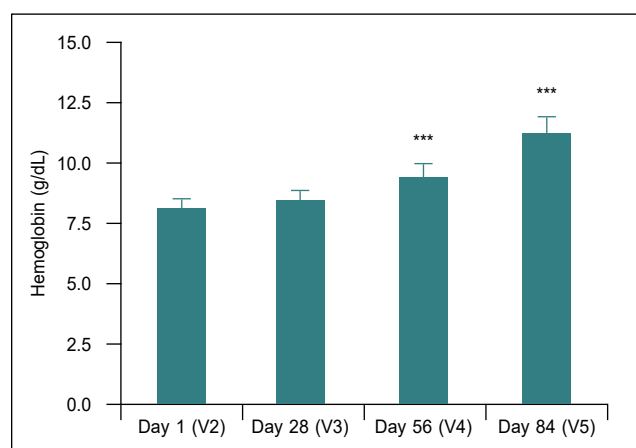


Figure 1. Comparison of mean change in hemoglobin level from Day 1 (V2) to different follow-up visits (n = 16).

Mean of hemoglobin at V2 was compared with Visits V3, V4 and V5 using one-way ANOVA. Comparison: V2 vs. V3, V4 and V5. Significance level ***p < 0.0001.

*P < 0.05, **P < 0.01, ***P < 0.001.

Assessment for anemia signs and symptoms

Anemia sign and symptom scores were assessed at Days 1 (V2), 28 (V3), 56 (V4) and 84 (V5) (Table 3). Results showed a significant reduction in anemia sign and

Table 3. Means of Anemia Sign and Symptom Scores at Different Visits

Parameters	Visit (V)	Mean (n = 16)	SD
Weakness	V2 (Day 1)	1.0	0.00
	V3 (Day 28)	0.73	0.46
	V4 (Day 56)	0.19	0.40
	V5 (Day 84)	0.0	0.0
Fatigue	V2 (Day 1)	1.0	0.0
	V3 (Day 28)	0.56	0.51
	V4 (Day 56)	0.0	0.0
	V5 (Day 84)	0.0	0.0
Breathlessness	V2 (Day 1)	1.0	0.0
	V3 (Day 28)	0.50	0.52
	V4 (Day 56)	0.0	0.0
	V5 (Day 84)	0.0	0.0
Pallor	V2 (Day 1)	1.0	0.0
	V3 (Day 28)	0.38	0.50
	V4 (Day 56)	0.0	0.0
	V5 (Day 84)	0.0	0.0

symptom scores from Day 1 (V2) to different follow-up visits. Mean changes in all anemia sign and symptom scores (except weakness score at Day 28) were found to be statistically significant (p < 0.0001) from Day 28 (V3) onwards compared to Day 1 (V2) (Table 4). Reduction in weakness score was found to be statistically significant (p < 0.0001) from Day 56 (V4) onwards.

Assessment of PGA

Assessment of PGA score was assessed at all assessment points (Table 5). Results showed that the PGA score was significantly (p < 0.001) reduced at Days 28, 56 and 84 compared to Day 1 (Table 6 and Fig. 2).

Safety Assessment

Assessment of general health symptoms

During the study period, the general appearance, eyes, ears, nose, throat, abdomen, heart and chest of all subjects were examined to look for any treatment-related abnormalities. No abnormalities were observed at any study visit.

Assessment of vital signs

Vital sign parameters of all subjects, including heart rate, systolic and diastolic blood pressure, were measured at

Table 4. Comparison of Mean Change in Anemia Symptom Scores from Baseline to Different Follow-up Visits (n = 16)

Parameters	Visit (V)	Mean score (mean ± SD)	Change from V1 (mean ± SD)	95% CI of Diff.
Weakness	V2	1.0 ± 0.0	-	-
	V3	0.73 ± 0.46	0.31 ± 0.48	-0.029 to 0.563
	V4	0.19 ± 0.40	0.81 ± 0.40***	0.521 to 1.104
	V5	0.0 ± 0.0	1.0 ± 0.0***	0.709 to 1.291
Fatigue	V2	1.0 ± 0.0	-	-
	V3	0.56 ± 0.51	0.44 ± 0.51***	0.190 to 0.685
	V4	0.0 ± 0.0	1.0 ± 0.0***	0.753 to 1.247
	V5	0.0 ± 0.0	1.0 ± 0.0***	0.753 to 1.247
Breathlessness	V2	1.0 ± 0.0	-	-
	V3	0.5 ± 0.52	0.50 ± 0.52***	0.251 to 0.749
	V4	0.0 ± 0.0	1.0 ± 0.0***	0.751 to 1.249
	V5	0.0 ± 0.0	1.0 ± 0.0***	0.751 to 1.249
Pallor	V2	1.0 ± 0.0	-	-
	V3	0.38 ± 0.50	0.63 ± 0.50***	0.384 to 0.866
	V4	0.0 ± 0.0	1.0 ± 0.0***	0.759 to 1.241
	V5	0.0 ± 0.0	1.0 ± 0.0***	0.759 to 1.241

IDA sign and symptom scores at baseline (V2) were compared with follow-up visits (V3, V4 and V5) using one-way ANOVA. Comparison: V2 vs. V3, V4 and V5. Significance level ***p < 0.001.

*P < 0.05, **P < 0.01, ***P < 0.001.

Table 5. Means of PGA Scores at Different Visits

Assessment	Visit (V)	Mean (n = 16)	SD
PGA score	V2	1.0	0.0
	V3	0.31	0.48
	V4	0.0	0.0
	V5	0.0	0.0

Table 6. Comparison of Mean Change in PGA Score from Baseline to Different Follow-up Visits (n = 16)

Assessment	Visit (V)	Mean score (mean ± SD)	Change from V1 (mean ± SD)	95% CI of Diff.
PGA score	V2	1.0 ± 0.0	-	-
	V3	0.31 ± 0.48	0.69 ± 0.48***	0.457 to 0.918
	V4	0.0 ± 0.0	1.0 ± 0.0***	0.769 to 1.231
	V5	0.0 ± 0.0	1.0 ± 0.0***	0.769 to 1.231

PGA score at Day 1 (V2) were compared with follow-up visits (V3, V4 and V5) using one-way ANOVA. Comparison: V2 vs. V3, V4 and V5. Significance level ***p < 0.001.

*P < 0.05, **P < 0.01, ***P < 0.001.

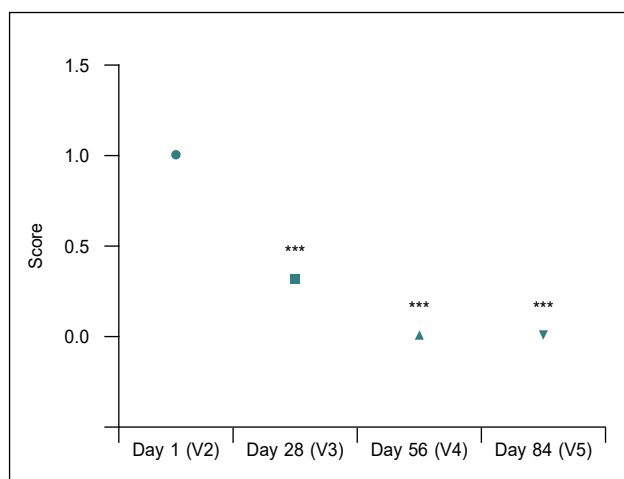


Figure 2. Comparison of mean change in PGA score from Day 1 (V2) to different follow-up visits (n= 16).

PGA score at V2 were compared with follow-up visits (V3, V4 and V5) using one-way ANOVA. Comparison: V2 vs. V3, V4 and V5. Significance level ***p < 0.001.

*P < 0.05, **P < 0.01, ***P < 0.001.

all assessment points (Table 7). The baseline (Day 1, V2) vital signs data were compared to the Days 28 (V3), 56 (V4) and 84 (V5). There was no significant difference in vital sign parameters between Day 1 and Day 84;

CLINICAL STUDY

Table 7. Mean Vital Signs at Different Visits

Parameters	Visits	Range (Min. – Max.)	Mean (n = 16)	SD
Heart rate (bpm)	V2	72-86	81.56	3.52
	V3	72-82	79.25	2.52
	V4	80-82	80.75	1.0
	V5	78-82	80.38	1.09
	SBP (mm/Hg)	V2	100-120	110.63
	V3	110-120	112.50	4.47
	V4	100-120	110.0	5.16
	V5	110-120	115.63	5.12
DBP (mm/Hg)	V2	70-80	72.50	4.47
	V3	70-80	74.38	5.12
	V4	70-80	76.25	5.0
	V5	70-80	73.75	5.0

Table 8. Comparison of Mean Change in Vital Signs from Baseline to Different Follow-up Visits

Parameters	Visit (V)	Mean ± SD (n = 16)	Change from V1 (mean ± SD)	95% CI of Diff.
Heart rate (bpm)	V2	81.56 ± 3.52	-	-
	V3	79.25 ± 2.52	-2.31 ± 4.35*	0.107 to 4.518
	V4	80.75 ± 1.0	-0.81 ± 3.75	-1.393 to 3.018
	V5	80.38 ± 1.09	-1.19 ± 3.78	-1.018 to 3.393
	SBP (mm/Hg)	V2	110.63 ± 4.43	-
V3		112.50 ± 4.47	1.88 ± 6.55	-6.514 to 2.764
V4		110.0 ± 5.16	-0.63 ± 6.80	-4.014 to 5.264
V5		115.63 ± 5.12	5.0 ± 6.32*	-9.639 to -0.361
DBP (mm/Hg)		V2	72.50 ± 4.47	-
	V3	74.38 ± 5.12	1.88 ± 7.5	-6.607 to 2.857
	V4	76.25 ± 5.0	3.75 ± 8.06	-8.482 to 0.982
	V5	73.75 ± 5.0	1.25 ± 7.19	-5.982 to 3.482

Vital signs data at Day 1 (V2) were compared to Days 28 (V3), 56 (V4) and 84 (V5) using the one-way ANOVA test. Comparison: V2 vs. V3, V4 and V5. Significance level *p < 0.05. **P < 0.01, ***P < 0.001.

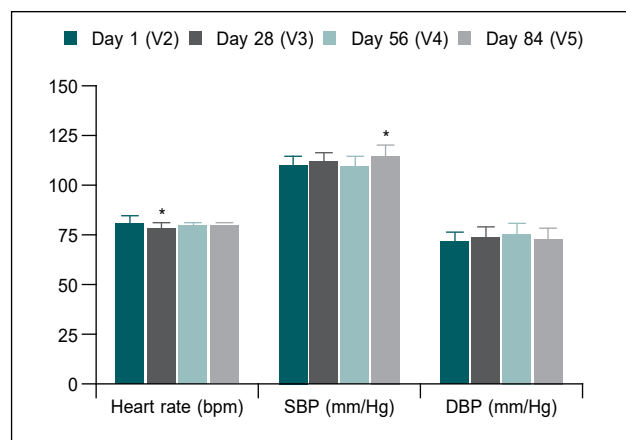


Figure 3. Comparison of mean change in vital signs from Day 1 (V2) to different follow-up visits.

Vital signs data at Day 1 (V2) were compared to Days 28 (V3), 56 (V4) and 84 (V5) using the one-way ANOVA test. Comparison: V2 vs. V3, V4 and V5. Significance level *p < 0.05.

P < 0.01, *P < 0.001.

all values were within the normal range (Table 8 and Fig. 3).

Adverse events

No adverse effects including serious adverse effects were observed during the study period.

DISCUSSION

W. somnifera or Ashwagandha is esteemed for its medicinal properties. It is commonly referred to as the "Indian Ginseng" due to its remarkable rejuvenating effects.¹¹ *W. somnifera* has been classified as a Rasayana (rejuvenation) in Ayurveda.¹² It is known to enhance vitality, energy, endurance and stamina, foster longevity and fortify the immune system, all without stimulating the body's reserves.¹¹ Studies have shown various properties of *W. somnifera* including antioxidant, anxiolytic, adaptogen, memory enhancing, antiparkinsonian, antivenom, sedative, diuretic, anti-inflammatory, antitumor and antistress properties.¹³

A study was conducted in anemic Albino Wistar rats to examine its antianemic activity. Following administration of the root extract of the herb, there was rapid and progressive recovery of the study animals due to the augmentation of erythropoiesis and defense against hemolysis caused by oxidative stress. The improvement in the hematological indices has been attributed to the iron content of the root extract. Iron plays a vital role in hemoglobin synthesis. These findings provide empirical support for the use of *W. somnifera* root extract in the treatment of anemia.¹⁴ The oral administration of a concentrated root extract of Ashwagandha at a high

dosage was found to be associated with an elevation in maximal oxygen consumption (VO_2 max) thereby improving cardiorespiratory endurance and enhancing quality of life in healthy athletic adults. Additionally, it was observed that Ashwagandha root extract positively influenced the red blood cell (RBC) count and hemoglobin levels. The increase in RBC count allows for improved oxygen transportation directly to the muscles during exercise, thus enhancing the athletes' aerobic capacity. Overall, these findings propose a plausible mechanism for the ergogenic effect of Ashwagandha root extract.^{11,15}

E. officinalis, also known as Amla or Indian gooseberry, is a rich source of vitamin C. It is often used as a Rasayana in Ayurveda for the management of IDA (*Pandu*).¹⁶ The other major phytoconstituents of *E. officinalis* include polyphenols (gallic acid, ellagic acid), tannins and flavonoids (rutin and quercetin).¹⁷ It has antioxidant, immunomodulatory, antipyretic, analgesic, cytoprotective, memory-enhancing, antitussive, gastroprotective, purgative and spasmolytic properties.^{18,19}

Phytates in food inhibit the absorption of dietary non-heme iron, whereas vitamin C enhances bioavailability of iron.^{16,20} The ascorbic acid enhances reduction of ferric iron to ferrous form leading to increase in iron absorption. It also prevents the inhibitory effect of phytates on iron absorption.²¹ The effect of the aqueous extract of fruit of *E. officinalis* on various hematological parameters was evaluated in Wistar albino rats. Following administration of the extract in doses of 250 mg/kg and 500 mg/kg body weight, a significant increase in packed cell volume, hemoglobin concentration, RBC, mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), mean corpuscular volume (MCV) and platelet count was observed compared to controls. The white blood cell (WBC) count also showed a marked increase at all doses administered. Other important findings of the study were reduction in total cholesterol and triglycerides.^{20,22}

A study was conducted in a tertiary care teaching hospital, to assess the impact of amloki on RBC, WBC and platelet count. A total of 43 pregnant women aged 18 to 36 years, between the 13th and 20th weeks of gestation and diagnosed with IDA were selected for this study. The participants were divided into two groups: Group A, which received oral iron and amloki supplementation, and Group B, which received only iron supplementation, for a period of 45 days. A significant increase ($p < 0.05$) in RBC count was observed in both groups following iron intervention. Furthermore, the iron + amloki supplemented group demonstrated

a significantly higher increase in RBC count compared to the group receiving only iron supplementation. This study also observed an increase in WBC count in the iron + amloki supplemented group and a decrease in platelet count in both groups, although these changes were not statistically significant. The study concluded that combination of oral iron and *E. officinalis* (amloki) supplementation leads to an increased blood RBC count in pregnant women with IDA.²⁰

A. racemosus or Shatavari is known as the "Queen of herbs" and is considered a health tonic and used as a rejuvenator. It improves longevity, vigor, mental function and boosts immunity. *A. racemosus* has antioxidant, anti-inflammatory, antiseptic and antimicrobial properties.²³ It also has potent adaptogenic activity, which reduces stress and protects against infection and illness.²⁴

A study was conducted with the chloroform:methanol (2:1) extract of *A. racemosus* in rats with experimentally induced anemia and thrombocytopenia. The doses used in the study were 250, 500 and 750 mg/kg given orally for a duration of 10 days. Oral administration of 750 mg/kg of the root extract resulted in substantial increase in the number of RBC and hemoglobin, while the MCH and total leukocyte count decreased. The bleeding and clotting time was also reduced in comparison to the heparin group. This study demonstrated that the root extract of *A. racemosus* possesses noteworthy antianemic and antithrombocytopenic properties.²⁵

Traditionally, *P. tuberosa* is a restorative tonic and is used for its antiaging and health-promotive activities.²⁶ It is an energizer, vital energy booster and immune booster.²⁷ The tubers and leaves are rich in phytoconstituents for example, puerarin, daidzein, genistein, quercetin, irisolidone, biochanin A, biochanin B, isoorientin and mangiferin, through which it exerts its beneficial activities mainly anti-inflammatory, antioxidant, anti-stress, nootropic, hypolipidemic, cardioprotective, among others.²⁸ The anti-inflammatory effect of extracts derived from *P. tuberosa* have also been attributed to the enhanced activity of the antioxidant enzymes present in RBCs, which act as the second-line of defense against oxidative stress. Glutathione is the first-line of defense against the damaging effects of oxidative stress. It effectively counteracts the harmful free radicals (FRs) directly and also in collaboration with other antioxidants like vitamins E and C.²⁹

CONCLUSION

The results of the present clinical study demonstrated that "Sangfer" is highly effective for the treatment of

anemia during pregnancy, as evidenced by the significant increase in the blood hemoglobin level, anemia sign and symptoms and PGA scores. Furthermore, during the 84-day treatment period, no significant changes in vital signs were observed. There were no treatment-related side effects reported by any of the study participants.

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