



A CLINICAL STUDY REPORT OF KVGAP'S HAEMOCARE SYRUP ON PANDU ROGA W.S.R TO ANEMIA

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ABSTRACT

Anemia is the most common deficiency disorder affecting a large population. It can be correlated with Pandu Roga described in Ayurvedic texts. A single-blind randomized clinical study was conducted in 30 patients with Anemia with KVGAP'S Haemocare Syrup. Patients were evaluated for the clinical parameters of weakness, fatigue, palpitation, effort intolerance, breathlessness, swollen feet and Hb level, before treatment, After 1 month and after 2 months (at the end of treatment). The results showed 87.18%, 82.81%, 95.35%, 90.32% and 94.44% in clinical features of weakness, fatigue, palpitation, effort intolerance, breathlessness and swollen feet respectively. Hb percentage improved to 17.09%. In the Overall effect of treatment, out of 30 patients in this study, 3 patients (10%) showed moderate improvement and 27 patients (90%) showed marked improvement. The overall effect of the treatment was 89.87%. Thus, KVGAP'S Haemocare syrup can be effectively used in the treatment of Pandu Roga w.s.r to Anemia

Keywords: Anemia. KVGAP'S Haemocare syrup, Pandu Roga

INTRODUCTION

About 30% or nearly one-third of the world's population is suffering from anemia¹. In India, prevalence is very high as compared to world prevalence. The prevalence of anaemia was 70% in children aged 6–59 months, 55% in females aged 15–49 years and 24% in males aged 15–49 years.²Anemia and iron deficiency are known to have several functional consequences. Many herbal ayurvedic haematinics are gaining popularity in the effective and safe treatment of Anemia. *Pandu roga*³ described in Ayurveda can be correlated with Anemia. KVGAPS Haemocare syrup is polyherbal ayurvedic syrup, manufactured and marketed by KVG Ayurveda Pharma and Research Centre, Ambateadla Sullia. It is enriched with ingredients like *Draksha*, *Kharjura*, *Ashwagandha*, *Gairika* etc. The composition of the formulation was done after meticulous research of the properties of its ingredients and to provide comprehensive treatment for *Pandu Roga* (Anemia). The study was done to evaluate the effect of Haemocare Syrup, in patients of *Pandu roga* w.s.r to Anemia.

Materials and Methods

Study design

A randomized, single-blind clinical study was conducted on 30 patients suffering from Anemia.

Inclusion Criteria

- Patients of either sex from 15 -60 years
- Patients with Hb level less than 12 gm/dl

Exclusion Criteria

- Pregnant/ Lactating women
- Severe Renal / Hepatic/ Cardiac disease
- Bleeding disorders
- History of chronic infection.

Selection of the drug

KVGAP'S Haemocare Syrup was manufactured in KVG Ayurveda Pharma and Research Centre, Ambateadka, Sullia adhering to the strict GMP guidelines.

Contents of KVGAP'S Haemocare Syrup

Contents of KVGAP'S Haemocare Syrup are presented in Table 1

Table 1: Each 5ml of the syrup contains

Drug	Botanical Name	Amount
<i>Draksha</i>	<i>Vitis vinifera</i>	187mg
<i>Kharjura</i>	<i>Phoenix sylvestris</i>	112 mg
<i>Ashwagandha</i>	<i>Withania somnifera</i>	75mg
<i>Bhoomiyamalaki</i>	<i>Phyllanthus niruri</i>	75mg
<i>Gairika</i>	<i>Red ochre</i>	75 mg
<i>Guduchi</i>	<i>Tinospora cordifolia</i>	75 mg
<i>Manjistha</i>	<i>Rubia cordifolia</i>	75 mg
<i>Mandhukaparni</i>	<i>Centella asiatica</i>	75 mg
<i>Punarnava</i>	<i>Boerhavia diffusa</i>	75 mg
<i>Sariva</i>	<i>Hemidesmus indicus</i>	75 mg
<i>Haritaki</i>	<i>Terminalia chebula</i>	60 mg
<i>Vibhitaki</i>	<i>Terminalia bellirica</i>	60 mg
<i>Amalaki</i>	<i>Emblica officinalis</i>	60 mg
<i>Yasthimadhu</i>	<i>Glycyrrhiza glabra</i>	56 mg
<i>Haridra</i>	<i>Curcuma longa</i>	37.5 mg
<i>Shunti</i>	<i>Zingiber officinale</i>	37.5 mg
<i>Vacha</i>	<i>Acorus calamus</i>	30 mg
<i>Pippali</i>	<i>Piper longum</i>	7.5 mg
<i>Sita</i>		2600 mg

Analytical parameters of KVGAP'S Haemocare Syrup

Colour- Blackish brown

Odour- Agreeable

Organoleptic characters

Taste- Sweetish

Nature of the preparation- Syrup

Table 2: Showing Physical and chemical parameters of KVGAP'S Haemocare Syrup

pH	4 to 6
Viscosity	5 to 10
Total solid	43 to 55
Sp. gravity	1.168 to 1.178
Total sugars	47 to 55 % w/w
Reducing sugar	1 to 8 % w/w
Non reducing sugar	40 to 50 % w/w
Refractive index	1.35 to 1.145
Brix value	45 to 52 %

Schedule of Treatment

30 Patients with Hb % less than 12gm/dl were randomly selected from OPD of KVG Ayurveda medical college and Hospital and also from Private Ayurvedic Practitioners. Patients were administered with KVGAP'S Haemocare Syrup as the sole drug at the dose of 10 ml Bid.

Duration of treatment: 2 months. Diet- Normal diet was advised in all cases. The assessment was done before treatment, after the end of 1 month and 2 months.

Laboratory investigations, Blood for Hb %.

Investigations were done at the attached biochemistry department of KVG Ayurveda medical college and Hospital.

Assessment Criteria

The results of the clinical study were assessed based on observations of clinical features and laboratory findings.

Clinical Assessment

The following parameters were mainly adopted for assessment before, at the end of 1 month and after the treatment.

Weakness, Fatigue, Palpitation, Effort intolerance, Breathlessness, Swollen feet.

Description of grades and their relationship with grade points

For statistical assessment of results some grades and grade points considering the severity of different

clinical features, have been used as follows:

Grading of clinical features

G 0 (Grade point 0) – No clinical feature/ symptom

G 1 (Grade point 1) - Mild clinical feature/ Symptom

G2 (Grade point 2) – Moderate clinical feature/ Symptom

G3 (Grade point 3) – Severe clinical feature/ Symptom

Overall assessment of the result

The results were assessed based on observations of clinical features and laboratory findings before, during and after treatment.

Very Good- Improvement 75% and above

Good- Improvement 50% and above but < 75%

Fair- Improvement 25 % and above but <50%

Poor- No improvement or marginal improvement < 25%

Results

In the present study, 30 patients suffering from Anemia fulfilling the inclusion criteria were studied and were randomly selected. Out of 30 patients, 12 patients were male and 17 females. Out of 30 patients, 11 patients were from the age group of 18-30, 10 patients were from the age group of 31-45, 9 patients were from the age group of 45-60.

Each patient was observed thoroughly and noted neatly. The observations are recorded, and necessary charts and graphs were made.

Table 3: Effect on Weakness in Anaemia

Symptom	Measures			%	S.D (+/-)	S.E (+/-)	t value	P-value	
	BT								
Weakness	2.60	One Month	1.27	1.33	51.28	0.479	0.089	15.23	<0.05
		Two Months	0.33	2.27	87.18	0.691	0.128	17.95	<0.05

Effect on Weakness:

Out of 30 patients with **Anemia**, all 30 were presented with **Weakness**. Results of the effect of KVGAP'S Haemocare syrup on weakness is shown in table No 03, Statistical analysis showed that the mean score,

which was 2.60 before treatment, was reduced to 1.27 after 1 month and reduced to 0.33 after 2 months with 87.18% improvement, and there is a statistically significant change. (P<0.05)

Results are graphically represented in figure No 01

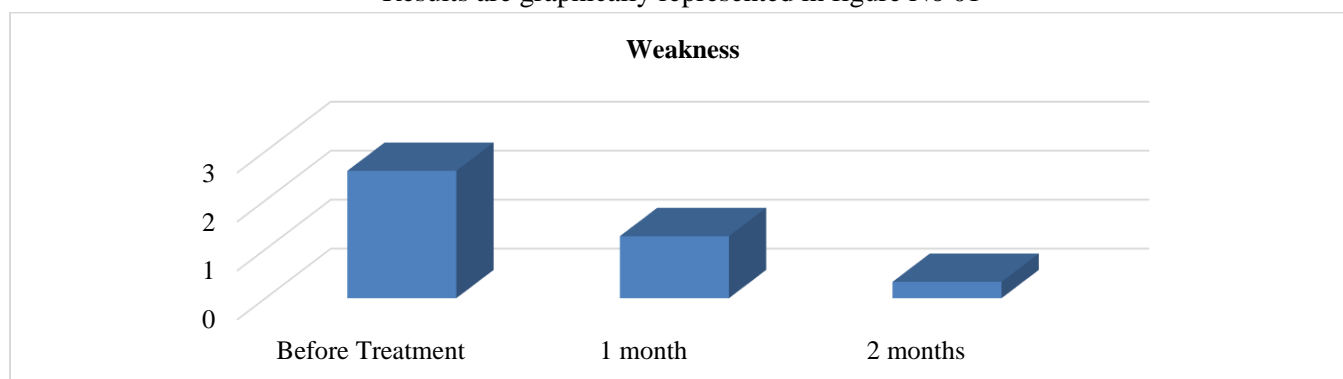


Table 4: Effect on Fatigue in Anaemia.

Symptom	Measures			%	S.D (+/-)	S.E (+/-)	t value	p-value	
	BT								
Fatigue	2.13	One Month	0.86	1.27	59.38	0.583	0.108	11.89	<0.05
		Two Months	0.36	1.77	82.81	0.626	0.116	15.46	<0.05

Effect on Fatigue:

Out of 30 patients with **Anemia**, 29 patients were presented with **fatigue**. Results of the effect of KVGAP'S Haemocare syrup on fatigue is shown in table No 04

Statistical analysis showed that the mean score, which was 2.13 before treatment, was reduced to 0.86 in 1 month and reduced to 0.36 after 2 months with 82.81% improvement, and there is a statistically significant change. (P<0.05).

Results are graphically represented in figure No 02

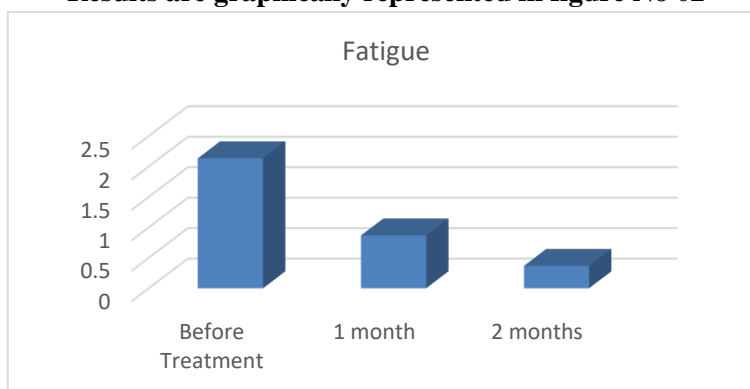


Table 5: Effect on Palpitation in Anaemia.

Symptom	Measures				%	S.D (+/-)	S.E (+/-)	t value	p-value
	BT								
Palpitation	1.43	One Month	0.63	0.80	55.81	0.610	0.113	7.18	<0.05
		Two Months	0.07	1.37	95.35	1.066	0.198	7.02	<0.05

Effect on Palpitation:

Out of 30 patients with **Anemia** 22 patients were presented with **palpitation**. Results of the effect of KVGAP'S Haemocare syrup on palpitation are shown in Table No 05. Statistical analysis showed that the

mean score, which was 1.43 before treatment, was reduced to 0.63 after 1 month and reduced to 0.07 after 2 months with 95.35% improvement, and there is a statistically significant change. (P<0.05). Results are graphically represented in figure No 03

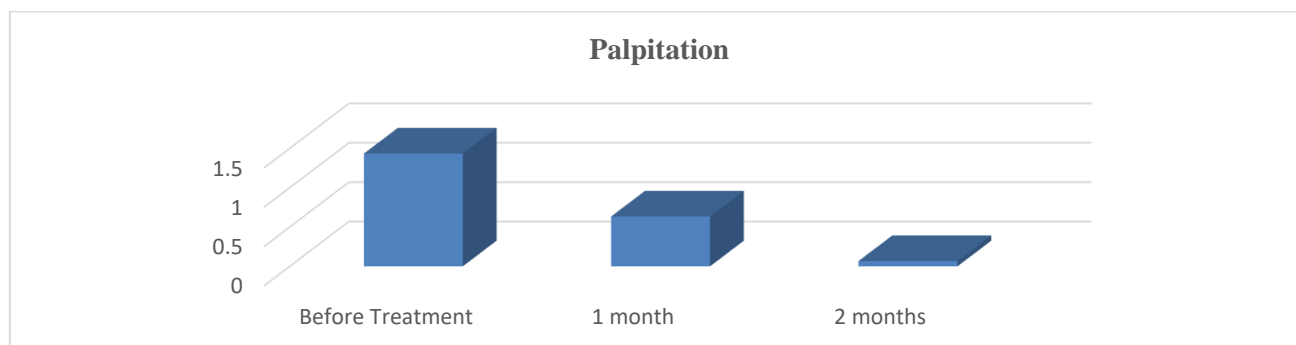


Table 6: Effect on Effort Intolerance in Anaemia.

Symptom	Measures				%	S.D (+/-)	S.E (+/-)	t value	p-value
	BT								
Effort Intolerance	1.03	One Month	0.33	0.70	67.74	0.596	0.111	6.43	<0.05
		Two Months	0.10	0.93	90.32	0.828	0.154	6.18	<0.05

Effect on Effort Intolerance:

Out of 30 patients with **Anemia** 22 patients were presented with **Effort Intolerance**. Results of the effect of KVGAP'S Haemocare syrup on **Effort Intolerance** are shown in Table No 06. Statistical analysis showed that the mean score, which was 1.03 before

treatment, was reduced to 0.33 after 1 month and reduced to 0.10 after 2 months with 90.32% improvement, and there is a statistically significant change. (P<0.05). Results are graphically represented in figure No 04

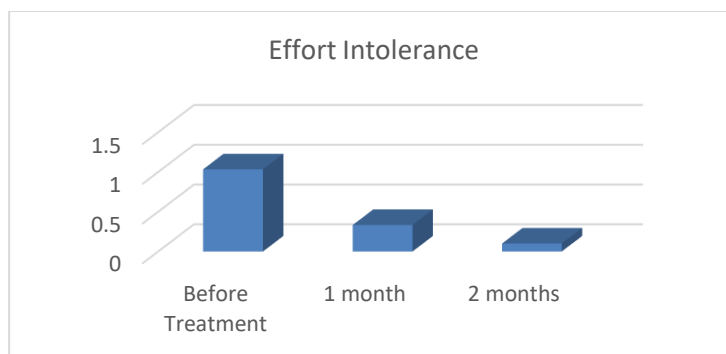


Table 7: Effect on Breathlessness in Anemia

Symptom	Measures				%	S.D (+)	S.E (+)	t value	p-value
	BT								
Breathlessness	0.60	One Month	0.13	0.47	77.78	0.507	0.094	5.04	<0.05
		Two Months	0.03	0.57	94.44	0.626	0.116	4.96	<0.05

Effect on Breathlessness:

Out of 30 patients with Anemia 15 patients were presented with **Breathlessness**. Results of the effect of KVGAP'S Haemocare syrup on **Breathlessness** are shown in Table No 07. Statistical analysis showed

that the mean score which was 0.60 before treatment was reduced to 0.13 after 1 month and reduced to 0.03 after 2 months with 94.44% improvement, and there is a statistically significant change. (P<0.05)

Results are graphically represented in figure No 05

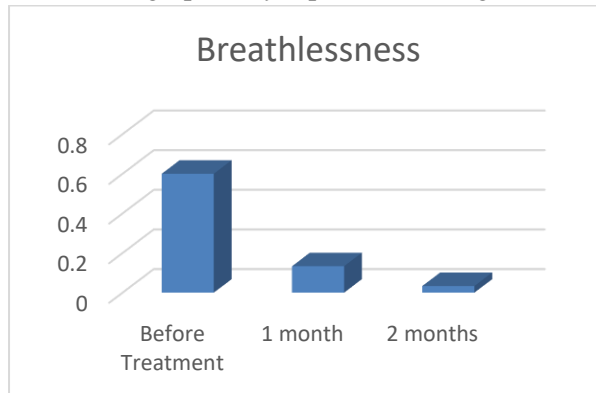


Table 8: Effect on Swollen Feet in Anemia

Symptom	Measures				%	S.D (+)	S.E (+)	t value	p-value
	BT								
Swollen Feet	0.57	One Month	0.14	0.43	76.47	0.568	0.106	4.18	<0.05
		Two Months	0.04	0.53	94.12	0.730	0.136	4.00	<0.05

Effect on Swollen Feet: Out of 30 patients with Anemia 15 patients were presented with **swollen feet**. Results of the effect of KVGAP'S Haemocare syrup on swollen feet are shown in Table No 08. Statistical analysis showed that the mean score which

was 0.57 before treatment was reduced to 0.14 after 1 month and reduced to 0.04 after 2 months with 94.12% improvement, and there is a statistically significant change. (P<0.05)

Results are graphically represented in figure No 06

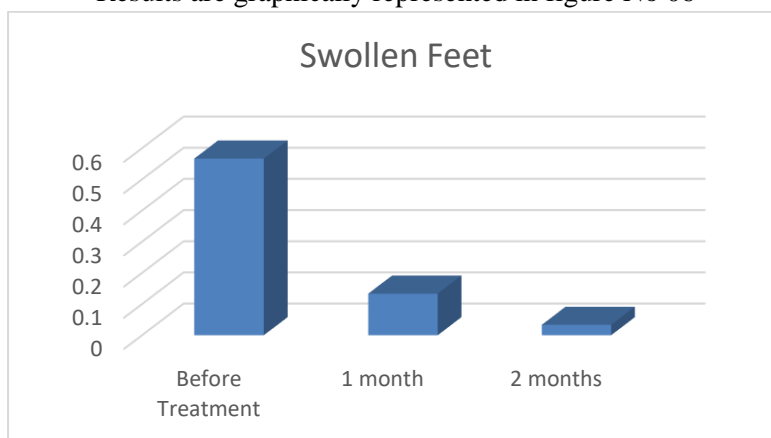


Table 9: Effect on Hb level in Anaemia

Symptom	Measures			%	S.D (+.)	S.E (+.)	t value	p-value	
	BT								
Hb	9.01	One Month	9.84	0.83	9.21	0.471	0.088	9.64	<0.05
		Two Months	10.55	1.54	17.09	0.798	0.148	10.57	<0.05

Effect on Hb:

This study consisting of 30 patients of Anemia with Hb % revealed the result of it as shown in Table No 09. Statistical analysis showed that the mean score

which was 9.01 before treatment was increased to 9.84 after 1 month and increased to 10.55 after 2 months with 17.09% improvement, and there is a statistically significant change. (P<0.05).

Results are graphically represented in figure No 07

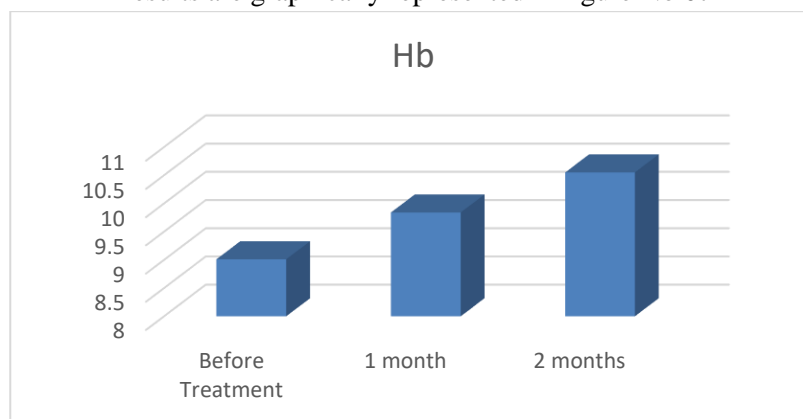


Table 10: Overall effect of treatment

OVERALL EFFECT OF TREATMENT		
Grading	Relief in Percentage	Relief in Patients
No Improvement	0- 25%	0
Mild Improvement	26 - 50 %	0
Moderate Improvement	51 – 75 %	3
Marked Improvement	76 – 100 %	27

In the Overall effect of treatment in Anemia, out of 30 patients in this study, 3 patients (10%) had shown

moderate Improvement and 27 patients (90%) got marked Improvement.

The overall effect of the treatment is 89.87%

Figure 8:

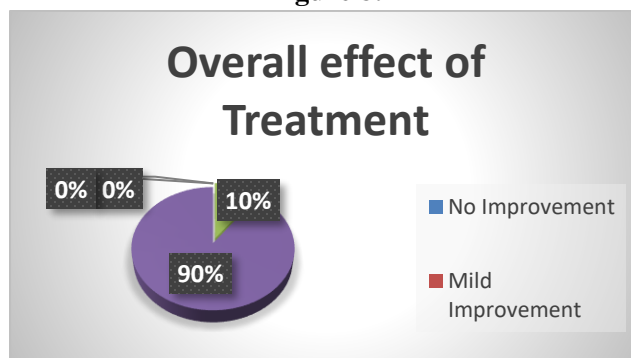


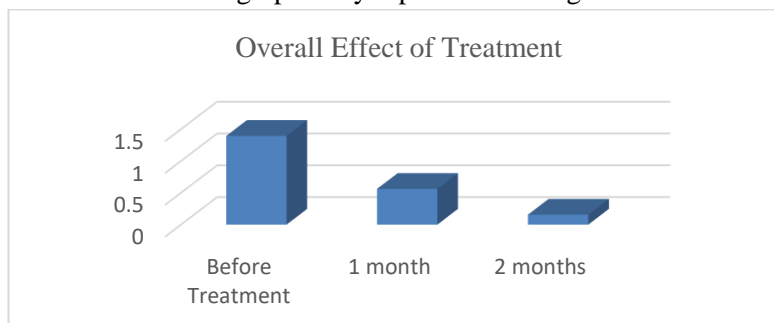
Table 11: Overall Effect of Treatment

BT	One Month	Two Months	SD	SE	T Value	P-Value
1.39	0.56	0.16	0.467	0.087	14.54	<0.05

The overall effect of treatment, statistical analysis showed that the mean score which was 1.39 before

treatment was reduced to 0.16 after treatment, and there is a statistically significant change. (P<0.05)

Results are graphically represented in figure No 08



DISCUSSION

Anaemia is the most prevalent deficiency disorder affecting both developed and developing countries significantly. Despite its severe ill effect on human health, it hurts the social and economic development of the country. Allopathic Haematinic supplements are reported of producing adverse effects, which are of concern. Considering the necessity of safer and effective Ayurvedic haematinic, KVGAP'S Haemocare Syrup was manufactured and a clinical study was conducted in 30 patients diagnosed with *Pandu Roga* (Anemia) After treatment with the trial drug for

2 months, all clinical assessment parameters: weakness, fatigue, palpitation, effort intolerance, breathlessness, swollen feet showed statistically highly significant improvement (87.18%, 82.81%, 95.35%, 90.32%, 94.44%, 94.12% respectively) at p-value <0.05. Clinical features of *Pandu Roga* are because of a decrease of Hb level and thereby reduction in oxygen supply to the tissues. By the treatment of KVGAP'S Haemocare Syrup, haemoglobin status improves, ensuring adequate oxygen supply to the tissues, improving metabolism and thus accomplishes improvement in clinical features. The main ingredient

of Trail drug, KVGAP'S Haemocare Syrup, *Kharjura* is a rich source of iron with the highest iron content (1,648 mg / 100g). The iron content in dates can increase the number of erythrocytes thereby increasing haemoglobin levels⁴. Apart from iron, the protein, carbohydrate and fat content in dates can help the process of haemoglobin synthesis. *Draksha* (Raisins) have one of the highest polyphenolic content and antioxidant ORAC levels compared to other traditional dried fruits. Many of the polyphenols in raisins are well assimilated and bioavailable. Raisin consumption reduces low-density lipoprotein (LDL) cholesterol, blood pressure and blood sugar, when compared to equal caloric carbohydrate snacks and is associated with a reduced risk of CVD⁵. *Ashwagandha* works as an adaptogen and stress reliever. *Bhumyamalaki* improves liver function and metabolism. *Gairika* is a natural iron supplement. *Guduchi* is potent immunomodulator. *Manjistha* contains a wide variety of antioxidants like alizarin, hydroxyl anthraquinones⁶ and rubiadin⁷. *Mandookaparni* has cognitive-enhancing and antioxidant properties^{8,9}. *Punarnava* has an antioxidant effect. *Sariva* also exhibits antioxidant effect¹⁰. *Amalaki* has ascorbic acid (Vitamin C) which has a significant effect on iron bioavailability from cereals and pulses in vitro¹¹. *Haritaki* has ferric reducing antioxidant activity¹² Therefore, iron absorption easily happens. *Vibhitaki* has immunomodulatory and antioxidant properties.¹³ *Yasthimadhu* is a potential anti anaemic drug.¹⁴ *Haridra* is an important ingredient in many *Pandukarma Yogas*. *Shunti*, *Vacha*, *Pippali* can act as bioavailability enhancers. Thus, the overall combination of anti anaemic properties along with immune modulator and antioxidant properties of ingredients of KVGAP'S Haemocare Syrup can help in improving clinical features of Anemia.

CONCLUSION

The clinical trial results showed that KVGAP'S Haemocare syrup showed significant results in improving clinical features of Anemia and also improving the Haemoglobin level without producing any

adverse effects, thus it can be used as a Haematonic supplement in the treatment of Anemia.

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