European Journal of Molecular & Clinical Medicine
ISSN 2515-8260 Volume 7, Issue 07, 2020

Protocol for Evaluation of comparative efficacy of Dietary supplement acquired from Kitchen Garden (Parasbag) and Gudharitaki Awaleha in Pandu Roga (Iron Deficiency Anemia)

Dr. Sadhana Misar Wajpeyi[1], Dr. Premkumar Badwaik[2] , Dr. Manoj Patil[3]

1. *Professor, Dept of Swasthavritta*
2. *HOD, Associate Professor, Dept of Swasthavritta*

Mahatma Gandhi Ayurved College Hospital & Research Centre, Salod (H), Datta Meghe Institute of Medical Sciences (Deemed to be University),Wardha (MS).

3. *Research Consultant, Jawaharlal Nehru Medical College, Datta Meghe Institute of Medical Sciences, Wardha.*

Corresponding Author:
Dr. Sadhana Misar Wajpeyi, Professor, Dept of Swasthavritta, Mahatma Gandhi Ayurved College Hospital & Research Centre, Salod (H), Datta Meghe Institute of Medical Sciences (Deemed to be University), Wardha (MS)
sadhanamisar@gmail.com, Mob.no. 9763732083

Abstract

Background: Pandu Roga is Pitta Pradhana Tridoshaja Vyadhi in which aggravated Pitta Dosha vitiates Kapha, Vayu, Rakta, Twaka, Mamsa and Ojas. It can be correlated with Iron deficiency Anemia, due to similarity in clinical features. Inadequate intake of iron rich food in diet is the main cause of Iron deficiency anemia.

Aim: Evaluation of effect of dietary supplement acquired from Kitchen garden with Gudharitaki Awaleha on RBCs, Hb%, MCV, MCHC, MCH for making Kelapur village anemia (Iron deficiency) free. Methodology: 120 subjects (60 in each) will be classified randomly into 2 parallel groups. Group A i.e. Trial group –Gudharitaki Awaleha 5 gm BD with Dietary supplement will be given after meal two times a day with lukewarm water for 90 days and Group B i.e. Control group – Gudharitaki Awaleha 5 gm BD will be given after meal two times a day with lukewarm water for 90 days. Assessment will be noted on 0 & 90 th day. Result: Variations will be seen in subjective as well as objective parameters and inferences. Conclusion: The effectiveness of Gudharitaki Awaleha with dietary supplement will be more than only Gudharitaki Awaleha

Keywords: Iron Deficiency Anemia, Gudharitaki Awaleha, Pandu, Kitchen Garden.

1. Introduction:-

Pandu Roga is Pitta Pradhana Tridoshaja Vyadhi. The decreased level of *Rasa* and *Rakta* which have the major functions of nourishment and providing support to the vital function give rise to the symptoms. Aggravated *Pitta Dosha* vitiates *Kapha*, *Vayu*, *Rakta*, *Twaka*, *Mamsa* and *Ojas. Vivarnata* of *Twaka* (discoloration of skin/Panduta) is the characteristic feature of *Pandu*. Other signs of *Pandu Roga* are *Agnimandya* (diminished appetite), *Aruchi* (tastelessness in food*)*, *Daurbalya* (general debility), *Bhrama* (giddiness) etc.[1]. It can be correlated with Iron deficiency Anemia, due to similarity in clinical features. Inadequate intake of iron rich food is the main cause of Iron deficiency anemia.

It is a condition having low concentration of hemoglobin (Hb) and decrease in the number of red blood corpuscles of the body [2].

Throughout the world, Iron deficiency anemia is considered as a major health issue, and even the WHO declared Iron deficiency as one of the commonest and widespread nutritional deficiencies throughtout the world today especially affecting the females and children [3].

Anaemia is multifactorial including dietary and non-dietary factors. Nutritional anemia is mainly caused by dietary deficiencies of minerals and vitamins like iron, folic acid, vitamin A, vitamin B_{12}, ascorbic acid and zinc. These nutrients deficiencies may be due to inadequate dietary intake and poor bioavailability of these micronutrients. Recommended dietary allowance for iron is 8 mg/day for adult men as well as for females after menopausal age, whereas it is 18 mg/day for pre-menopausal women. Therefore, selection of iron-rich diet and better bioavailability techniques are crucial to meet the demand. Iron is one of the essential micronutrients needed for synthesis of Hemoglobin [4]. Green leafy vegetables and fruits are the best source of minerals and vitamins. The average productivity of these crops is much lower (48.6 q/ha) than state (52.4 q/ha) and national productivity (171.1 q/ha). Cultivation of variety of fruits and vegetables rich in micronutrients in the kitchen garden is the most effective, easy and safe source of getting fresh and healthy food. This practice is particularly more beneficial in rural regions where people have low purchasing power and distant markets. Kitchen gardening directly provides food and nutritional security by making easy availability to food that can be harvest instantly, prepared, and can be used by all members in the family, every day or whenever required. These vegetables also provide taste, palatability, better digestibility to us and increase the appetite. According to Daily requirement, the daily need of vegetables is 300 gm/person which mainly include green leafy and other vegetables with tubers and roots. Vegetables are suitably grown in kitchen gardens as they are mostly short duration crops. A family can take vegetables from these kitchen gardens round the year [5]. A Kitchen Garden is a small plot near to the house used for growing a variety of vegetables and fruits according to the season since early times. From Kitchen Garden one can get pure, fresh, organic, cheap, and healthy fruits and vegetables, a rich source of micronutrients. Also they are free from all chemicals and poisons by providing organic manure and kitchen waste with using good seed. Kitchen gardening directly provides food and nutritional security and easily accessible to all when needed [6].

Dietary supplement acquired from Kitchen Garden (Parasbag) which mainly consists vegetables and fruits. The Kitchen Garden kit will include green leafy vegetables like spinach, fenugrik, White amaranth, red amaranth, white goosefoot, green coriander, fruits like brinjal, tomato, lady finger, Cluster beans, green chili, Long beans /Cow-pea beans, climbers like cucumber, pumpkin, ridge gourd, bottle gourd, bitter gourd, root and tubers include beet, carrot and radish, Papaya and drumsticks. This will help in increasing awareness regarding dietary habits by

increasing intake of vegetables and fruits from kitchen garden for preventing anaemia in rural India. Haritaki is indicated for the treatment of Pandu roga in almost all the classics of Ayurveda. Guda Haritaki yoga is one of the important medicines indicated in Panduroga in Bharat Bhaisajya Ratnavali. Various research study conducted on Guda Haritaki yoga proved its efficacy in Panduroga[7] .

Need of the study

As per the National Family Health Survey, 53.2% of population of non-pregnant female and 50.4% of pregnant one between age of 15-49 years were found to be anemic in 2016, whereas only 22.7% men were anemic in this age group [8].

In majority of patients having iron deficiency anemia are mild and there is no any apparent complications are seen. But prolonged deficiency can leads to severe adverse effects on the health, mental growth, and efficiency of an individual worldwide. There are multiple strategies for correcting iron deficiency like iron rich dietary supplement, oral and injectable iron preparation and blood transfusion. But all have limitations due to adverse effects [9]. Hence, to prevent and to combat iron deficiency by selection of diet rich in iron is very important. India is considered as the second position in production of fruits and vegetables however its utilization is very less particularly among the people of rural region, which may be due to the ignorance, lack of knowledge, poor accessibility of vegetables and fruits and poor purchasing power in lower income group.

Healthy dietary habit like consuming fruits and vegetables having micronutrients is an easy, cheap and efficient way to deal with nutritional deficiency. Vegetables and fruits are rich sources of nutritional bioactive compounds.

In KG vegetables and fruits are grown organically are free from toxic chemicals but there is lacking of its knowledge and skill. The use of organically grown vegetables and fruits could contribute significantly supply of mineral and vitamins and also associated with decreasing occurrence of anemia related to nutritional deficiencies in poor population [10, 11].

To deal with the multiple causes of anemia efficiently, there is need of collaboration and coordination among various related sectors like Dietary, health, water, cleanliness and hygiene, as well as, poverty mitigation, farming, industry and education and various groups such as government and nongovernmental organizations and the private divisions.

Mission Samriddhi (MS) is a social impact enterprise which aims to achieve holistic sustainable rural development & has been working in Wardha and Yavatmal in the theme of Panchayat Empowerment, Health, Education and Livelihood for the last 3 years.

Mission Samriddhi (MS) wishes to make one village anemia free on pilot basis for which they have identified Kelapur Tq. Wardha for the project. Kelapur has a population of 1026 and is located on Deoli – Pulgaon road with about 30 km distance from Wardha. They are promoting the activity of kitchen gardens for the last three years with the support of MSRLM. For making village Anemia Free they have distributed the seed and conducted the training on kitchen garden. There is a need to encourage and to create awareness regarding consumption of organically grown vegetables and fruits for keeping good health and combating nutritional deficiency disorders like Iron Deficiency Anemia. The aim to evaluate the effect of dietary supplement acquired from Kitchen garden with Gudharitaki Awaleha on RBCs, Hb%, MCV, MCHC, MCH for making Kelapur village anemia (Iron deficiency) free.

Hence this study is planned in collaboration with Mission Samriddhi (MS) to evaluate the comparative efficacy of dietary supplement acquired from Kitchen Garden (Parasbaga) and *Gudaharitaki Awaleha.*

Trial structure design-

Randomized open reference standard controlled single blind Double armed Study. Interventional study of two similar group set having equal ratio.

Interventions- Table 1

Group	Sample size	Intervention	Dose and Frequency	Anupan	Duration	Follow-up
A	60	Dietary supplement acquired from KG and Gudharitaki Awaleha	5gm BD	Water	90days	Monthly
B	60	Gudharitaki Awaleha	5gmBD	Water	90days	Monthly

Methodology

Study location

The assessment of study will be directed in MGACH & RC, Salod (H), Wardha.

Eligibility standards- Patients between the age group 16-50 years of either sex having Hb % in the range of 7 to 11gm/dl and having iron deficiency without other causes of Anemia will be included in the study. Known cases of Thalassemia, Sideroblastic anemia, Anemia due to Malignancies, Hereditary sickle cell, Aplastic anemia, hemolytic anemia, pregnant & lactating women, known cases of bleeding disorders and females with menstrual disorders will be excluded.

Standards for terminating and changing assigned interferences

If any unwanted & untoward side effects observed, if symptoms aggravated during treatment and patients no more willing to continue the treatment will be withdrawn from the study. Free treatment will be given to the patient if any untoward effects will appear. To check drug adherence, there will be monthly follow up throughout 90 days of treatment.

Follow up duration – Monthly to check the drug adherence.

Primary Results- Assessment of the outcome of trial drug on RBCs, Hb%, MCV, MCHC, MCH will be done before and at the end of the treatment.

Statistical study

The observations will be analyzed by using chi square test and student unpaired t test.

Time Period till Trial Ends

The subject will be observed throughout treatment of 90 days.

Follow up duration- 0, 30^{th}, 60^{th} and 90^{th} day

Time period of registration, interferences

Drug will be administered from starting of the treatment to 90 days.

Recruitment

120 (60 in each group) subjects will be recruited by simple random selection Lottery method. PI and Co- PI will assign and register the subjects

Methods

Information gathering, organization, and examination.

Data gathering techniques

Assessment parameters: Subjective Parameters like *Vivarnata* (pallor of skin*), Agnimandya* (diminution of Agni), *Daurbalya (*general debility), *Shwasa* (exersional dyspnoea)

Objective parameters like RBC, Hb%, MCV, MCH and MCH

The assessment will be done according to the gradations of subjective parameters on day 0 and 90 day. Subjects will be kept in contact and monthly follow up for drug adherence will be taken.

Expected Result

Gudharitaki Awaleha with Kitchen garden will reduce *Vivarnata* (pallor of skin*), Agnimandya* (diminution of Agni), *Daurbalya (*general debility), *Shwasa* (exersional dyspnoea) and will increase RBC, Hb%, MCV, MCH and MCH and will give symptomatic as well as therapeutic relief.

Discussion

Gudharitaki Awaleha contains *Gud* (*jaggery*) and *Haritaki* (*Terminalia chebula.* Retz.) which is indicated in Panduroga in Bharat Bhaishajya Ratnavali. *In all Ayurveda classics Haritaki* is indicated for *Pandu roga*. Deepana pachana properties of Haritaki helps in correcting Agnimandya, the main cause of Panduroga. In *Pandu roga there* is dushti of *rasa and rakta dhatu* [12]. *Haritaki* is a *rasayana* drug that helps in correcting dhatudushti and promoting formation of good dhatu. It possesses antioxidant, immunomodulatory, antibacterial and Anthemintic activities[13]. Jaggery (Gud), a product of sugarcane, is rich in minerals mainly Iron and Calcium. Each 100 g of jaggery contains 10-13 mg of Iron. Recommended Dietary Allowances (RDA) of Iron in man is 17mg per day and in women it is 21mg per day.[14] Research studies conducted on Jaggery in iron deficiency anemia proved its efficacy in increasing Hb%. Hence it will help in increasing Hb% [15,16,17]. Prevalence of anemia globally is evident from a number of studies [18-22]. Studies on anemia have been reported by Baliga et. al [23], Jaiswal et. al[24] and Singh et. al.[25]. Few of the related studies from this region were reviewed [26-30].

The organically produced products like fruits and vegetables from Kitchen Garden are rich source of micronutrients that will help in reducing nutritional deficiency of iron, calcium and will help in increasing Hb%. It also helps in increasing absorption of iron. Hence this study is undertaken to evaluate efficacy of Dietary supplement acquired from Kitchen Garden (Parasbag) in the management of Panduroga.

Data Management

The information entrance coding will be completed by PI

Statistical approaches

The data will be analyzed by using chi square test and student unpaired t test.

Ethics Moral and Distribution

Research ethics agreement and also endorsement from research ethics board has been reserved. Ref.No. MGACHRC/IEC/October-2020/149

Consent or Any Agreement

The written consent will be obtained from the subject before commencement of the trial.
During the trial the privacy of all subjects will be preserved.

Dissemination strategy

The information will be disseminated by publication in Journal. Author's eligibility strategies and any proposed use of specialized authors

Informed Agreement Resources

With complete material data model agreement consent form and any other associated certification will be allotted to subjects.

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