



**ORIGINAL RESEARCH PAPER**

**Medicine**

**A SINGLE BLIND RANDOMIZED CONTROLLED TRIAL ON EFFECTIVENESS OF RUBIA TINCTORUM Q IN ANAEMIA AMONG COLLEGE GOING FEMALE STUDENTS OF SEMI URBAN AREAS IN SANGAREDDY**

**KEY WORDS:** Anaemia, Rubia tinctorum Q, Placebo, hemoglobin level.

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**ABSTRACT** Anaemia is a condition of having a lower-than-normal number of red blood cells or quantity of hemoglobin. Anaemia diminishes the capacity of the blood to carry oxygen. Patients with anaemia may feel tired, fatigue easily, appear pale, develop palpitations, and become short of breath. Rubia tinctorum mother tincture is a homeopathic mother tincture that is indicated for the treatment of anaemia and undernourished conditions. Rubia tinctorum mother tincture, has been found to be effective in treating anaemia, kidney and bladder calculi. This project, help to know the efficacy of Rubia tinctorum mother tincture in treating anaemia.

**INTRODUCTION**

Globally Anaemia affects 1.62 billion people; it's a major health problem (1). According to WHO expert group, a hemoglobin level of 10-11g/dl has been defined as early anaemia, a level below 10g/dl as marked anaemia (2). "Severe anaemia" was generally defined as Hb < 7g/dl. Anaemia is the widest spread micro-nutrient deficiency affecting all age group irrespective of gender, caste or religion. In India, this silent emergency is rampant among women belonging to reproductive age group (15-49 years) (3).

A girl during and after her puberty, will have rapid growth and development with a significantly increased need for macro and micronutrients, otherwise an anemic girls become the next generation of anemic mothers. Hence, the health of adolescent girls and college going females demands special attention.

Homoeopathic mode of treatment, with the use of medicines made of natural substances, is very effective in treating anaemia. Homoeopathic medicines will provide capacity to the body that assimilates the iron in the food we take, so it is a natural process that will increase hemoglobin percentage (4). Rubia is a genus of flowering plants. It belongs to the family: Rubiaceae, kingdom: Plantae, Genus: Rubia. The mother tincture is prepared from root of madder plant (13). Rubia is indicated for splenic anaemia (5). It's also suitable for anaemia due to under nourished conditions, amenorrhoea

English Name: Common Madder  
Botanical Name: Rubia Tinctorum (7)

**AIMS AND OBJECTIVES**

- To verify the efficacy of Rubia Tinctorum Q in anaemia
- To establish the improvement by follow up analysis.

**NEED OF THE STUDY**

The prevalence of anaemia is disproportionately high in the developing countries, due to poverty, inadequate diet, worm infestations, pregnancy/lactation and poor access to the health services (8). The world's adolescent population and young females of child bearing period is facing a series of serious nutritional challenges which are not only affecting their growth and development but also their livelihood as adults (9). Inadequate nutrition during adolescence an early adult can have serious consequences throughout their productive years of life and beyond (10).

Very often, in India, girls get married and pregnant even before the growth period is over, thus doubling the risk for anaemia (11).

According to the WHO, the highest number of individuals affected by anaemia is observed in non-pregnant women aged 15- 49 years (12). Anaemia is a leading public challenge in India so we want to bring out the action of at least one rare remedy for anaemia, the present study may help in future to treat anaemia.

**SCOPE / ACCOMPANYING MERITS OF THE RESEARCH**

Rubia tinctorum which belongs to the family, Rubiaceae .it is having action on splenic anaemia (19) and undernourished conditions, is taken into account for the study. As there are no previous studies for the same on considering the potential action of the remedy, Rubia tinctorum showing non-toxic effect, can be a landmark in the history of homeopathy in treating anemia. There by the remedy can be a locale for the welfare of public.

**METHODOLOGY:**

Written Consent is taken from each and every patient who had participated in the study, the treatment plan had explained to each patient in their own language.

**STUDY SETTING:**

A sample of 60 cases are randomly selected from patient who is having decreased hemoglobin count visiting our MNRHMC collegiate OPDs/IPD, Case taking along with hemoglobin percentage were done. Consent form is taken from each and every patient who had participated in this study and the treatment plan had explained to each patient in their own language.

**STUDY DESIGN AND TYPE:**

Single blinded, simple random sampling, Interventional study.

**SAMPLE SIZE:** 60 patients

**Procedure:**

Two groups (One group with Rubia Tinctorum Q, Another group with placebo in liquid form (14), each group with 30 cases.

**Categorization of patients:**

**Group 1** – Rubia tinctorum Tincture, patient is advised to take 10 drops in 1-ounce water two times daily (administered for 30 patients) i.e. 30 ml is given per week.

**Group 2** – Placebo in liquid form 30 ml is given, patient is advised to take 10 drops of given medicine in 1-ounce water two times daily (administered for 30 patients). To both group dietary management is advised.

**SELECTION OF TOOLS:**

- MNRHMC case record format.
- Hemoglobin percentage report .

**QUALITY CONTROL AND QUALITY ASSURANCE**

All medicines is procured from GMP certified pharmaceutical companies approved by the institutional ethical committee. Drug is acquired from standard homoeopathic pharmacy and drugs are stored as per the rules of Indian homoeopathic pharmacopoeia.

**ETHICAL ISSUES**

Ethical clearance has been obtained from college ethical committee before starting the study.

**INCLUSION CRITERIA:**

- Age between 18-24
- Only females

**EXCLUSION CRITERIA:**

- Males.
- Hemoglobin concentration below 7 gm %.
- Age below 18 and above 24.
- Anaemia with complication.
- Pregnant and lactating women.
- Thalassemia, sickle cell anaemia, haemolytic anaemia.
- Anaemia due to hemorrhoids, worm infestation.

**STEPS FOR ADMINISTRATION:**

After case taking of patients who is presenting with symptoms of anaemia, we had sent them for preliminary laboratory investigations and if their hemoglobin percentage is less than 12, to one group we had given Rubia tinctorum Q. To another group we had given Placebo in liquid form. To both group dietary management is advised. Patient is also advised to visit OPD of collegiate hospital once in a week. Hemoglobin percentage is checked once in a month for 6 months. Improvement is assessed by changes in symptoms and hemoglobin percentage before and after the study.

**OBSERVATION AND RESULT:**

Outcome is assessed by comparing the symptoms and hemoglobin concentration before and after treatment. 60 Patients with anaemia are included in this study. All these cases are divided into 2 groups.

**Group 1** – Rubia tinctorum Tincture, patient is advised to take 10 drops in 1-ounce water two times daily (administered for 30 patients) i.e. 30 ml is given per week.

**Group 2** – Placebo in liquid form 30 ml is given, patient is advised to take 10 drops of given medicine in 1-ounce water two times daily (administered for 30 patients).

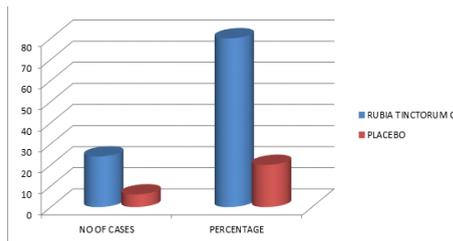
To both group dietary management is advised.

Each group contains 30 patients. All these cases are followed up for 6 months. The statistical analysis and corresponding observations are made based on the data so obtained.

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**TABLE 1: DISTRIBUTION OF CASES ACCORDING TO IMPROVEMENT IN RUBIA TINCTORUM Q GROUP AND PLACEBO GROUP.**

IMPROVEMENT	NO OF CASES	PERCENTAGE
RUBIA TINCTORUM Q	24	80
PLACEBO	6	20



**Results:**

Rubia tinctorum Q group

- Average (x d) : (-7)
- Sample size (n) : 30
- Sample SD (Sd) : 3.300993
- Skewness : 0.46837
- Skewnes Shape : Potentially Symmetrical (pval=0.077)
- Normality p-value : 0.4609

PLACEBO group

- Average (x d) : 0.266667
- Sample size (n) : 30
- Sample SD (Sd) : 2.333169
- Skewness : 0.753802
- Skewnes Shape : Potentially Symmetrical (pval=0.077)
- Normality p-value : 0.0007813
- Outlier (Sd) : -4, -3, -3, -3, -2, -2, 2, 2, 2, 3, 4, 6, 6

Group name:

- Group 1 – Rubia tinctorum Q group.
- Group 2 – Placebo group.

Sample average (X):

- Group 1 – (-7).
- Group 2 – 0.2667

Sample size (n):

- Group 1 – 30.
- Group 2 – 30.

Sample σ (S):

- Group 1 – 3.300993.
- Group 2 – 2.333169.

**Two sample t-test (Welch), using T distribution (DF=52.1882) (two-tailed) (validation)**

**1. H<sub>0</sub> Hypothesis:**

Since p-value < α, H<sub>0</sub> Is rejected. The average of Rubia's population is considered to be not equal to the average of the Placebo's Population.

In other words, the difference between the average of the Rubia and PLACEBO population is big enough to be statistically significant.

**2. P-value:**

P-value equals 1.70322e-13, (p(x≤T) = 8.51610e-14). This means that the chance of type I error (rejecting a correct H<sub>0</sub>) Is small: 1.703e- 1.3 (1.7e- 11%). The smaller the p – value the more it supports H<sub>1</sub>. H<sub>0</sub> is rejected and H<sub>a</sub> is accepted so, by this study we can know that Rubia tinctorum Q is effective in treating anaemia.

**DISCUSSION:**

Life is the noblest gift of god, and health is one of its greatest accompanying blessings. To recover health when lost and to preserve it in its integrity is the principle aim of the physician. Anaemia is the most condition of young college going female students.

In this research 60 cases of anaemia are taken among college going female students of semi urban areas in sangareddy. Among 60 cases, 30 cases are under treatment of Rubia

tinctorum Q and other 30 cases are given placebo in liquid form. All the cases are taken between the age group of 18 – 24 years and only females are included. Males and anaemic females with other medical illnesses and pregnant and lactating women are excluded in this research.

This study included patients with age group between 18 – 24 years. According to this study, the most common age group having anaemic condition is 19 years and the most common associated symptoms with anaemia is pallor, fatigue, muscular weakness and out of 30 cases of Rubia tinctorum Q, 24 cases were improved, 4 cases persist as same and 2 cases were aggravated. And out of 30 cases of placebo, 6 cases were improved, 16 cases persist as same and 8 cases were aggravated. It was known that rubia tinctorum Q is effective in treating anaemia.

**CONCLUSION:**

In Rubia tinctorum Q group out of 30 cases, 24 cases were improved, 4 cases Persist as same before and after treatment and 2 cases got aggravated than before treatment and in placebo group out of 30 cases 6 cases were improved, 16 cases persist as same before and after treatment and 8 cases got aggravated.

So more number of cases were improved in Rubia tinctorum Q group than placebo group so it is known that that Rubia tinctorum Q is effective in treating anaemia.

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