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A PROTOCOL FOR SYSTEMATIC REVIEW OF HOMOEOPATHIC INTERVENTIONS IN IRON-DEFICIENCY ANAEMIA

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Abstract
Background: In India, iron-deficiency anemia (IDA) is a significant health issue for women. This study reviews at clinical trials of Homoeopathic treatment for IDA to assess their effectiveness and provide evidence. Objectives: The primary objective of the study is the systematic review of selected studies and published clinical data in view of efficacy of Homoeopathic interventions in the management of IDA. Materials and methods: We retrieved 9 studies from the different databases and internet sites searches. The 9 articles were included in current review. This systematic review was done under the guidelines established by PRISMA – "Preferred Reporting Items for Systematic Reviews and Meta-Analyses." Full articles of potentially eligible studies obtained and independently evaluated for inclusion in the review based on the participants (inclusion criteria). Data extraction forms for individual study was prepared. This review can help health authorities create better health policies more effectively.

Keywords: Ferrum phosphoricum, Constitutional medicines, Iron deficiency anaemia (IDA), Homoeopathy, Haemoglobin (Hb).

Introduction:

Anaemia is a health issue where decreased red blood cells (RBC) or not enough hemoglobin than the normal adult. This can cause problems for people all around the world and is one of the most common nutrition-related problems. It affects anyone but is especially common in pregnant women and young children. This condition brings both health and social problems, impacting the lives of many.[1] The most common type of anemia worldwide is called iron deficiency anemia (IDA). The main reasons for causes for IDA are: poor eating enough iron-rich foods, less absorbing iron because of certain substances in the diet, when our body needs more iron, like during growth or pregnancy / lactation, heave blood loss like from heavy periods or because of parasites or infections, having other deficiencies in vitamins like A, B12, folate, riboflavin, and copper, which can also make anemia more likely.[2]

Globally, anaemia affects 1.62 billion people, which corresponds to 24.8% of the population.[2] According to World Health Organization (WHO), anaemia, has been defined by the as "a condition in which the number of red blood cells (RBCs) or their oxygen-carrying capacity is inadequate to meet physiologic demands of the body, which vary by sex, age, smoking, and pregnancy status".
In a survey from 2010 in India, it was found that a lot of people had a type of anemia called iron-deficiency anemia (IDA). This problem was very common, with over 95% of children, teenage girls, and pregnant women having anemia. Among these groups, teenagers had it the worst, with nearly 98% of them having anemia. And of those teenage girls, more than a quarter of them had severe anemia.[3]

According to the National Family Health Survey in India: Many Indian children have problems with their weight, growth, and nutrition. This issue is more severe in India compared to any other country in the world. Also, 7 out of every 10 young children have anemia. More than half of women (55%) and about a quarter of men (24%) in India are anemic. Among women, 39% have mild anemia, 15% have moderate anemia, and 2% have severe anemia. For men, 13% have mild anemia, 10% have moderate anemia, and 1% have severe anemia. Anemia is a widespread concern in India, affecting roughly 50% of the population. Different parts of India show varying rates of anemia. The highest prevalence is among women, with over 60% affected in regions like Jharkhand, Bihar, and the Northeastern states. Among children, anemia is found throughout India, ranging from 38% in Goa to 78% in Bihar.[4]

Prevention of iron-deficiency anemia (IDA) requires addressing all the factors that can cause it. This involves various strategies, including Increasing Iron Intake, Food Fortification: Adding iron to commonly consumed foods can help increase iron intake in the population. Iron Supplementation and improving health services by access to healthcare and medical advice is crucial for identifying and managing IDA. Sanitation: Better sanitation and hygiene practices can help reduce the risk of infections, which are factors contributing to IDA. Among these strategies, iron supplementation is a primary method for treating and preventing IDA.[5]

Homeopathic treatment for anemia focuses on improving the body's ability to absorb and use iron rather than directly supplementing iron intake based on recommended dietary allowances. In homeopathic practice, medicines like Ferrum phosphoricum 3X (FP) and Ferrum metallicum 3X (FM) are often used to treat anemia. These medicines are commonly employed by homeopathic practitioners, either alone or in combination with other remedies, for the treatment of anemia in people of all ages. However, it's important to note that specific clinical trials or studies assessing the effectiveness of FP or FM in iron-deficiency anemia (IDA) have not been conducted. Homeopathic treatments are typically based on individualized assessments by practitioners and may not always align with conventional medical approaches.[6]

Homeopathy is one of the most widespread and most effective forms of complementary or alternative medicine. Although exact data on the frequency of use of homoeopathy in anaemia patients is not available, surveys among general practitioners, indicates that a significant proportion might seek additional advice from homoeopaths. The aim of this systematic review was to evaluate whether homoeopathic medicine Ferrum phosphoricum have a therapeutic action on the Iron deficiency anemia because no systematic review has yet been done to evaluate the evidence regarding homoeopathic treatment strategies in anaemia. Ferrum phosphoricum is a specific homoeopathic medicine for Anemia which increases the haemoglobin level and it also break the tendency of low serum ferritin levels in blood. Ferrum phosphoricum attract the oxygen gives tonicity to circular fibers of vessels to contract and thus equalizing the circulation & also has action on intestinal villi to absorb, regulation of bowel movements, utilization of nutrients, micronutrients & reduction in iron intolerance. Thus Ferrum phosphoricum improve iron absorption from dietary sources or iron supplements and increases haemoglobin levels. Objectives The objective of this review was to

evaluate the efficacy and effectiveness of homoeopathic medicine Ferrum phosphoricum in Iron deficiency anaemia.

Objectives

Primary objective of the present study includes systematic review of selected studies and systematic review of the published clinical data in view of efficacy of Homoeopathic interventions in the management of IDA. Secondary objective of the present study includes meta-analysis of the published clinical data in view of safety and efficacy and effectiveness in the management of IDA.

Review Question

The review question includes what is the relative efficacy and safety of Homoeopathic Constitutional Medicine and or Ferrum Phos treatment modalities for IDA management.

Materials and Methods

The search and selection criteria outlined in the strategy are aimed at conducting a comprehensive search on the topic of anaemia and Homoeopathy. Here is a breakdown of the strategy:

Strategy for Comprehensive Search:

Conducted computerized literature searches to comprehensively identify studies on anaemia and Homoeopathy (RCT, non RCT).

Databases Searched:

National Medical Library (PubMed), Google Scholar, Elsevier, Science Direct, IJRH (Indian Journal of Research in Homeopathy), International Journal of Homoeopathic Sciences, National Journal of Integrated Research in Medicine from 2015 to till date (2023).

Search Terms:

Basic search terms for Homoeopathy: "Homoeopathy" or "Homoeopathic drugs" or "Homoeopathy".
Basic search terms for Anaemia: "anaemia", iron deficiency anaemia.

Selection of Studies:

Included studies that focused on Homoeopathic medicines and anaemia and had full-text articles available.
Excluded studies involving in vivo/in vitro studies, additional medical therapy, or anaemia treated with therapies other than homeopathy.

Table 1:

Author and Year Publication	Study design	Aim/ objective	Sample Size	Outcome Parameter	Intervention	Conclusion
PrashantTamboli et.al, 2015, India. [8]	Experimental study single blind randomized placebo control trial	To understand the efficacy of Ferrum Phosphoricum 6X in anemia during antenatal care.	60	Ferrum Phosphoricum 6x 2 tablets tds along with iron supplements improves Hb thus reduceing the risk of anaemia during the 2nd and 3rd trimester of pregnancy. It also helps in sustaining the Hb levels during change in trimester. It has shown result without any adverse effect of Ferrum Phos 6X during pregnancy.	Ferrum Phos 6X 2 tables TDS along with iron supplement produced statistically significant increase in Hb% as compared with only iron supplements	The result shows that there is an increase in mean Hb level of 0.27 gm% in Ferrum Phos group while there is decrease in mean Hb level by 0.23 gm% in the only iron supplement group.
Dr. H. Venkatesan[9] Dec 2018	Randomized clinical trial	To determine the efficacy of Homoeopathic medicine FerrumMetallicum 6X in increasing the Haemoglobin Concentration of 30 Paediatric Iron	30	The Haemoglobin Concentration of the patients before and after the prescription of Ferrummetallicum 6X for 3months are tested statistically by using Paired „t" Test.	Homoeopathic medicine Ferrum metallicum 6X was prescribed in the form of 1 Grain tablets. 2 tablets per oral route three times a day for three months were given to each patient. They were	Statistically there exists a significant difference in the Hb concentration of Paediatric IDA patients before and after administration of the

		Deficiency Anaemia patients. Statistical assessment of the same using Paired 't' test.			also advised to eat Iron Rich Food.	Homoeopathic medicine Ferrum metallicum 6X.
Dr. D. B. Sharma, 2018 [10]	A Randomized Placebo Contorlled Study	To assess the efficacy of Lecithin, a homoeopathic preparation in cases of Iron Deficiency Anaemia in adolescent girls. To assess the efficacy of the study drug in relieving symptoms associated with anaemia. To assess the efficacy of the study drug in improving quality-of-life (QOL) in anaemic adolescent girls. To assess the improvement or changes, if any, in necessary investigations performed at the beginning and end of study especially Hb level.	50	The outcome measures were changes in the blood Hb levels at a timeline of three months and six months. The effect size was considered as increasing of Hb level by a minimum of 2-3 g/Dl respectively. Thus, cases where this increased Hb levels were observed were ascribed as 'improved' and the rest as 'not improved'. The study end-point was increasing Hb levels following intervention. The primary safety end-point was any adverse event during the study in any of the groups.	50 anaemic adolescent girls were selected for the study. From the 50 patients selected for the study 25 patients were selected randomly and were given the study drug in 3X potency form whereas remaining 25 patients were treated with placebo in the form of non-medicated tablets. It was a non-blind open study.	Patients who were given Lecithin 3X showed greatly improved Hb levels. Thus cases of Iron Deficiency Anaemia in adolescence can be managed by administering a Homoeopathic medicine such as Lecithin known to have action on the RBC's. Lifestyle modifications like diet and regimen, physical exercise boost and have an added advantage along with medicinal treatment.
Anil Khurana, Renu Mittal, Padmalaya Rath et al 2020 [11]	Single blind Randomized clinical trial	The objective of this study is to identify efficacy of Ferrumphosphoricum3X (FP) and Ferrummetallicum3X (FM) in changing haemoglobin (Hb) levels in school-going children, 12–14 years of age with Iron Deficiency Anaemia (IDA)	160	Children enrolled were divided into two groups, i.e., those having mild anaemia (Hb between 11 and 11.9 g%) and having moderate anaemia (Hb between 8 and 10.9 g%). Children in both the groups were allotted serial numbers separately and randomised into two groups, i.e., FP group and FM group by using computer-generated random numbers	Children are given ferrum met 3x and ferrum phos 6x by computer randomization.	Significant increase in Hb was seen in children with moderate anaemia in FP group (9.95 ± 0.749–10.97 ± 1.51). Increase in Hb in other groups was not significant.
Dr. Justin K Jose and Dr. Sarika ES 2023[12]	Randomized clinical trial	To study the presentation & etiology of Iron Deficiency Anemia in women of reproductive age group. Efficacy of Homoeopathic management in Iron Deficiency Anaemia in women of reproductive age group.	30	On comparing the score before and after treatment the means were 12.73 and 6.33 and the variances were 14.68 and 15.74 respectively. The data showed a positive correlation of 0.43 and the statistical value obtained on't' test is 8.46 which is higher than Table value (1%) 1.69 and (5%) 2.045.	The application of Homoeopathic Medicines on the basis of symptom totality	According to the study, 83.33% (25 cases) show improvement & 16.67% cases (5 cases) show no improvement. This was statistically interpreted and a marked reduction was seen in the post test scores when compared to pretest scores. The calculated't' value is greater than table't' value. Homoeopathic medicines are effective in management of Iron Deficiency Anemia in women of reproductive age group.
Dr. Parth Aphale 2017[13]	Non randomized	The objective of this study is to identify efficacy of Ferrumphosphoricum3X	30	The Haemoglobin Concentration, Iron level, Reduction in the symptoms.	Homoeopathic medicine Ferrum metallicum 3X was prescribed	The statistical analysis proves that Homoeopathy is significantly useful in these 30 cases of Iron Deficiency AnemiaOut of 30 cases 24 cases i.e. 80% showed marked improvement in symptoms. So Ferrum Phos 3X is very much useful in treatment of Iron Deficiency
Dr. Jignesh J Doshi*, Dr. Pranav Shah, 2019 [14]	Non randomized	To evaluate the efficacy of Homoeopathic medicines in cases of Anemia. To evaluate the	30	1. Cure: Feeling of mental & physical wellbeing with disappearance of all	the medicines were prescribed based on the similarity between the totality of symptoms of a	Out of 30 cases we get the improved result in 18 patient, moderate result in 8

		miasmatic background in cases of Anemia.		sign & symptoms of anaemia with normalization of Hb without any relapse. 2. Improvement: Improvement in the sign & symptoms of anaemia with increase of Hb compared to previous one but not up to normal limit. No Improvement: No improvement in any sign & symptom.	given case and symptoms of the remedy prescribed	patient and in 4 cases the response of treatment is not good. Out of 30 cases taken for most cases were found to be having predominant Psora miasmatic phase.
Dimple Bhalla1, Nidhi Arora 2023[15]	Non randomized	The aim of study is to gain knowledge about anemia and role of Ferrum Phosphoricum remedy in treatment of anemia in order to relieve the suffering of humanity.	100	The outcome measures were assessed on the basis of the clinical parameters and also by the improvement of the patient as a whole.	Maximum cases 6X potency was prescribed in 44 patients i.e. 44 %, followed by 30 CH potency prescribed in 32 patients i.e. 32 % and 200CH potency prescribed in 24 cases i.e. 24 %.	This was a study with positive result. It helps me in exploring possible literature available bout the study. It gave me opportunity for application of Ferrum Phosphoricum medicine on patients of Iron Deficiency Anemia. Homoeopathy is the only science which not only relief symptoms but can also prevent further complications.
Gagandeep Kaur, Sunil Kumar, Vinay Kumar[16] 2021	Non randomized	1. To study the effect of homoeopathic medicine in patients of anaemia. 2. To determine the individual effect of homoeopathic medicine in cases of anaemia.	100	In this study, 09 cases (09%) observed with marked improvement, and 38 cases (38%) moderate improvement, 42 cases (42%) mild improvement and remaining 11cases (11%) showed no improvement at all. In this way overall 89% (09% +38%+ 42%) cases showed positive results.	In this study, it is observed that females (75%) are more prone to suffer from anaemia than males (25%). This could be due to loss of menstrual blood every month in females a Miasmatic analysis of the cases was done on the basis of presenting complains, past history, family history and patient's mental and physical constitution. As far as the miasmatic background is concerned, in this study out of 100 cases maximum cases of Anaemia were attributed to Psoric miasm i.e. 68 cases (68%), Psoro-sycosis was observed in 23 cases (23%) & Psoro-syphilis in 9 cases (9%).	This study showed positive effect in increasing the hemoglobin concentration by using homoeopathic medicines in Aanemic patients.

Search results

The search resulted in the inclusion of nine studies in the current review. The selection criteria were applied to these studies. Studies were excluded for the following primary reasons: they were only abstract articles, they were in vivo and vitro studies. In the end, the review included five randomized studies and four non-randomized studies.

Study Characteristics:

Characteristics regarding the participants in the review. To summarize, the participants in the reviewed studies were divided into various age groups and categorized based on their hemoglobin (Hb) levels and diagnoses related to anemia. Here is a breakdown of the participant characteristics in the studies:

Randomized Control Trials (RCTs):

a. Study 1:

Participants: Antenatal care for individuals between the second and third trimester.

Diagnosis: Mild to moderate anemia (Hb% = 7-10 gm%).

b. Study 2:
Participants: Pediatric age group between 5-10 years.
Diagnosis: Hb% = 8-10.4 gm%.
c. Study 3:
Participants: School-going children aged 12-14 years.
Diagnosis: Anaemia categorized into mild (Hb 11–11.9 g%) and moderate anaemia (Hb between 8 and 10.9 g%).
d. Study 4:
Participants: Schooling going children aged 12-14 years.
Diagnosis: Hb% = 8-11 gm%.
e. Study 5:
Participants: female age group between 14 – 49 years.
Diagnosis: Hb% = 8-11 gm%.

Non-Randomized Studies:
a. Study 6:
Participants: Adolescent age group between 17-20 years.
Diagnosis: Based on Hb%, Iron level, and symptoms of IDA.
b. Study 7:
Participants: 13 – 30 years of age group and another 51years & above.
Diagnosis: Inclusion based on Hb = 9-11gm%.
c. Study 8:
Participants: Adult age group between 10-18 years.
Diagnosis: Inclusion based on Hb = 8-11gm%.
d. Study 9:
Participants: Age group between 1-60 years.
Diagnosis: Inclusion based on Hb = 8-11gm%.
These studies encompass a range of age groups and severity levels of anemia, providing a comprehensive understanding of anemia in different populations.

Data Analysis
Investigators (including statistics consultant) was analysed data. The investigator is independently screen all citations and abstracts identified by a primary comprehensive search to sort out potentially eligible trials. Full articles of potentially eligible trials shall be obtained and independently evaluated for inclusion in the review based on the types of participants (inclusion criteria).
Data extraction forms for individual study is prepared. This include (1) methods used in the study (randomization/allocation concealment/blinding/sampling and sample size calculation/ length of follow-up), (2) participant characteristics of individual studies (along with disease characteristics/number of participants randomized/number of participants completing follow-up/reasons for withdrawal from the study), (3) interventions (treatment protocol administered/formulations used/Standard Operative Procedures (SOPs) administered/adverse events during the protocol), and (4) outcomes (in terms of safety/effectiveness/efficacy/improvement in quality of life). This systematic review was followed strictly under the established guidelines by PRISMA – "Preferred Reporting Items for Systematic Reviews and Meta-Analyses.[16]

Discussion
After searching so many databases, the nine studies related to the effectiveness of various treatments on iron deficiency anemia, particularly in different populations and with different Homoeopathic remedies. The five randomized controlled trials showed the effectiveness of Ferrum phosphoricum, lecithin and or Homoeopathic constitutional medicine in iron deficiency anaemia. The more detailed explanation of the studies and their implications are as follows:

Study 1: This randomized controlled trial suggests that Ferrum Phosphoricum 6X is effective in reducing the risk of iron deficiency anemia during the second and third trimesters of pregnancy. It also indicates that this treatment sustains hemoglobin (Hb) levels throughout pregnancy without adverse effects.
Study 2: This study was conducted on school-going children and found that Ferrum Phosphoricum has the capacity to increase hemoglobin levels in cases of anemia.
Study 3: In this study, patients with iron deficiency anemia were treated with Ferrum Metallicum 6X for about three months. The results showed an 80% positive effect in increasing hemoglobin concentration.
Study 4: A study on adolescent girls suggests that Lecithin has the capacity to increase hemoglobin levels in cases of anemia.
Study 5: Another study on adolescent girls found that constitutional Homoeopathic medicine has the capacity to increase hemoglobin levels in cases of iron deficiency anemia.
This review also included four non-randomized controlled trials (non-RCTs) suggesting that the effectiveness of a standardized homoeopathic medicine.
Study 6 & 7: Two studies of Non-RCT suggest that standardized Ferrum phosphoricum may be effective in increasing hemoglobin levels in iron deficiency anemia.
Study 8 & 9: other two non-RCT studies show that constitutional Homoeopathic medicine is effective in increasing hemoglobin levels in anemia. Constitutional medicine is a personalized approach in Homoeopathy where the remedy is chosen based on the individual's overall constitution (whole physically, mind and emotionally symptoms).
Despite the positive findings from these studies, the study concludes that there is insufficient data available on the effectiveness of Ferrum phosphoricum and or Constitutional medicine in treating anemia. This suggests that more research is needed to establish its efficacy definitively.
In Homoeopathy, remedies are highly individualized, and their effectiveness can vary from person to person. It's important to note that Homoeopathic treatments are often considered alternative or complementary therapies and may not be supported by mainstream medical consensus. As the review suggests, further studies are needed to better understand the potential benefits of Ferrum phosphoricum and other Homoeopathic treatments in managing anemia.

Conclusion

The research study suggests that Homoeopathic constitutional medicine and Ferrum phosphoricum or Lecithin increase hemoglobin levels in patients with iron deficiency anemia (IDA). While this implies a potential benefit, it is essential to highlight that further research is necessary to establish their effectiveness, given the current limited evidence, underscoring the need for additional research in this area.

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