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Therapeutic efficacy of *Majoon-e-Aarad Khurma* (poly-herbal formulation) in anaemia associated with hypothyroidism: A randomized placebo-controlled clinical trial

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Hypothyroidism and anaemia frequently coexist and may complicate clinical management, particularly in patients who experience intolerance or difficulty with conventional therapy. The present study was undertaken to evaluate the therapeutic efficacy of *Majoon-e-Aarad Khurma*, a traditional Unani polyherbal formulation, in anaemia associated with hypothyroidism. A single-blind, randomized, placebo-controlled clinical trial was conducted on 50 participants, who were allocated in a 2:1 ratio to receive either *Majoon-e-Aarad Khurma* or placebo for 45 days. Hematological parameters including hemoglobin (Hb), red blood cell count (RBC), packed cell volume (PCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), mean corpuscular volume (MCV), and red cell distribution width (RDW) were assessed as primary outcomes, while thyroid hormone levels (T3, T4) and thyroid-stimulating hormone (TSH) were evaluated as secondary outcomes. Although some within-group changes were observed, no statistically significant improvement was found in hematological parameters or thyroid hormone profile when compared with placebo. The findings suggest that *Majoon-e-Aarad Khurma*, when used as an adjunct for 45 days, did not produce significant therapeutic benefit in anaemia associated with hypothyroidism under the conditions of the present study. Further studies with larger sample size, longer duration, and more targeted patient stratification may be required to better evaluate its clinical potential.

Keywords: Anaemia, Hypothyroidism, *Majoon-e-Aarad Khurma*, *Su'al Qinya*, Traditional herbal therapy, Unani medicine

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Anaemia and hypothyroidism frequently co-exist, with hypothyroid patients often presenting with various types of anaemia. In India, anaemia is a significant public health concern, affecting approximately one-third of women of reproductive age[1]. Anaemia is defined as a condition in which the number of red blood cells or the hemoglobin concentration within them is lower than normal[2], leading to symptoms such as fatigue, shortness of breath, and impaired cognitive function. Recent studies continue to demonstrate a substantial burden of anaemia among patients with hypothyroidism, with reported prevalence ranging from 26% to 67% across different populations[3-5]. Normocytic normochromic anaemia is the most common morphological type, reflecting impaired erythropoiesis due to thyroid hormone deficiency[4,5]. Hypothyroidism exacerbates anaemia by impairing erythropoiesis through mechanisms such as bone marrow suppression, reduced erythropoietin production, altered iron metabolism, and nutrient deficiencies[3,6]. Furthermore, recent evidence has demonstrated a significant inverse correlation between serum thyroid-stimulating hormone (TSH) levels and hemoglobin concentration, supporting a biological gradient between thyroid dysfunction severity and hematological impairment[5]. Together, these conditions can significantly reduce patients' quality of life and complicate long-term management.

Levothyroxine is the standard treatment for hypothyroidism and can normalize thyroid function and improve anaemia. However, many patients experience intolerance to this medication, presenting with symptoms like anxiety, tachycardia, and restlessness[7-9]. Furthermore, anaemia management in hypothyroid patients often requires iron supplementation, which can interfere with levothyroxine absorption, leading to a therapeutic challenge[7,10]. Given these limitations, the search for alternative therapies that are both effective and better tolerated is critical.

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In Unani medicine, anaemia (*Su'al Qiniya*) and hypothyroidism are both classified as diseases of cold temperament (*Sue-mizaj barid*). Anaemia is believed to result from a cold alteration in the liver's temperament (*Sue-mizaj jigar barid*)[11-15], which impairs the liver's digestive function (*hazm-e-kabdi*)[12,16], while hypothyroidism is considered a disorder of cold and phlegmatic temperament (*Sue-mizaj barid balghami*)[17]. In line with the Unani principle of *Ilaj bil Zid* (treatment by opposites), conditions of cold temperament are treated with remedies of hot temperament. *Majoon-e-Aarad Khurma*, a polyherbal Unani formulation composed of *Phoenix dactylifera*, *Elettaria cardamomum*, *Piper longum*, *Cinnamomum zeylanicum*, *Zingiber officinale*, *Trapa bispinosa*, *Myrtus caryophyllus*, *Acacia nilotica*, *Prunus amygdalus*, *Pistacia vera*, *Juglans regia*, *Cocos nucifera* in specified proportions, (Table 1) has traditionally been used as an aphrodisiac. However, it is also rich in nourishing ingredients such as *Phoenix dactylifera* (dates), *Prunus amygdalus* (almonds), *Cocos nucifera* (coconut), and *Piper longum* (long pepper), which are described in Unani literature as possessing *Ḥar* (hot) temperament and *Muwallid-i-Dam* (blood-producing) or nutritive properties[18-21]. Since the formulation is predominantly composed of *Ḥar* drugs, and considering its overall nutritive composition, it was considered to have a theoretical basis for evaluation in conditions such as anaemia associated with hypothyroidism. In addition, previous studies on some of its individual ingredients have indicated nutritional, antioxidant, and hematinic potential, which further supports the rationale for the present study.

This study aims to evaluate the efficacy of *Majoon-e-Aarad Khurma* as an adjunct therapy for anaemia associated with hypothyroidism. Given the increasing interest in traditional medicines and their role in integrative healthcare, this research contributes to the understanding of alternative management strategies for these conditions, with the potential to improve patient outcomes and quality of life. By assessing haematological measures, we seek to determine whether *Majoon-e-Aarad Khurma* can serve as a safe and effective alternative for patients who struggle with conventional treatments.

Materials and Methods

Study design

A randomized, single-blind, placebo-controlled clinical trial was conducted from April 2021 to March 2022 to assess the efficacy of *Majoon-e-Aarad Khurma*, a traditional Unani polyherbal formulation, in improving anaemia-related outcomes in hypothyroid patients.

Sample size

The sample size was calculated for comparison between two groups using hemoglobin as the primary outcome measure, based on data from a previous study[22]. Assuming a two-sided significance level of 5%, power of 80%, pooled standard deviation (σ) of 2.36, expected mean difference (d) of 2.1, and an allocation ratio of 2:1 (test: placebo), the required sample size was calculated as 45 participants in total. To account for an anticipated dropout rate of 10%, a total of 50 participants were recruited. Accordingly, participants were randomized in a 2:1 ratio between the test group and the placebo group.

Table 1 — Composition of *Majoon-e-Aarad Khurma*[15]

S. No.	Name Of Drug	Scientific Name	Standard Qty (g)	Approx. amount per 1 g formulation
1.	Khurma	*Phoenix dactylifera* (Linn.)	250 g	54.35 mg
2.	Khajoor	*Dried Phoenix dactylifera* (Linn.)	500 g	108.70 mg
3.	Ilaichi Khurd	*Elletaria cardamomum* (Maton.)	10 g	2.17 mg
4.	Peepal Kalan	*Piper longum* (Linn.)	2 g	0.43 mg
5.	Daarchini	*Cinnamomum zeylanicum* (J.Presl.)	10 g	2.17 mg
6.	Zanjabeel(sonth)	*Zingiber officinale* (Rosc.)	10 g	2.17 mg
7.	Singhara Khushk	*Trapa bispinosa* (Roxb.)	500 g	108.70 mg
8.	Qaranfal	*Myrtus caryophyllus* (Linn.)	5 g	1.09 mg
9.	Gond Keekar	*Acacia nilotica* (Linn.)	500 g	108.70 mg
10.	Maghz Badam Shireen	*Prunus amygdalus* (Batsch var.)	75 g	16.30 mg
11.	Maghz Pista	*Pistacia vera* (Linn.)	75 g	16.30 mg
12.	Maghz Akhrot	*Jugulans regia* (Linn.)	75 g	16.30 mg
13.	Maghz Narjeel	*Cocos nucifera* (Linn.)	75 g	16.30 mg
14.	Qiwam Shakar Safaid	*Saccharum officinarum* (L.)	2500 g	543.48 mg
15.	Sat lemu	*Citric acid*	3 g	0.65 mg
16.	Natroon banjawi	*Sodium benzoate*	10 g	2.17 mg

Study population

Participants were recruited from outpatient departments at NIUM hospital, Bengaluru, based on the following criteria:

Inclusion criteria

- Aged 20-60 years
- Diagnosed with hypothyroidism on medication, with TSH levels ranging from normal to threefold higher than the upper limit of the reference range
- Mild to moderate anaemia (Hb: 8-11.9 g/dL in women, 8-12.9 g/dL in men)[23,24]

Exclusion criteria

- Severe anaemia (Hb < 8 g/dL)
- Abnormal gastrointestinal/genitourinary blood loss
- Uncontrolled diabetes mellitus or other serious systemic illnesses
- Known secondary causes of anaemia
- Pregnant and lactating women

The study was intended to evaluate anaemia associated with hypothyroidism in a clinical setting and was not restricted to a single biochemical subtype of anaemia. Participants showing any adverse effects or noncompliance with the treatment were withdrawn.

Trial registration

The trial was registered with the Clinical Trials Registry of India (CTRI/2021/02/030898) on 1/2/2021.

Randomization and blinding

Participants were randomized using a computer-generated sequence, with a 2:1 ratio favouring the test group. The randomization sequence was generated by the statistician. The principal investigator allocated the participants in the respective group according to the randomization sequence and delivered the intervention to all the participants on every follow-up. The participants were blinded to the intervention. Both the test formulation and placebo were similar in appearance and texture, packed in opaque similar containers with careful measures taken to maintain blinding.

Intervention

All the randomised participants were provided with the treatment based on the allocated group. *Majoon-e-Aarad Khurma* was prepared following a standard Unani method, resulting in a semi-solid formulation[25]. All ingredients used in the preparation of the test formulation were procured from the institute's pharmacy and verified as per institutional standards before preparation. Representative specimens of the constituent drugs were retained and deposited in the Drug Museum-cum-Herbarium, Department of Ilmul Advia, National Institute of Unani Medicine (NIUM), Bengaluru, under institutional reference number 120/M/Res/2021. The formulation was prepared in a single batch to ensure uniformity and dispensed under controlled conditions. The placebo was prepared using wheat flour and sugar syrup and was designed to resemble the test formulation in semisolid (*Majoon*) form, with comparable appearance and texture. Participants in the control group received 10 g of placebo daily before breakfast for 45 days, identical to the dosing schedule of the test group.

Assessment and follow-up

Each patient was assessed fortnightly at baseline, 15, 30, and 45 days. Primary outcomes included hemoglobin (Hb), red blood cell count (RBC), packed cell volume (PCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), mean corpuscular volume (MCV), and red cell distribution width (RDW). Secondary outcomes included thyroid hormone levels (T3, T4, and TSH), measured at baseline and after 45 days.

Statistical analysis

Data were analysed using SPSS version 20.0. Normality was assessed with the Kolmogorov-Smirnov test. Continuous variables were expressed as means ± standard deviation (SD), and group comparisons were performed using independent and paired Student's t-tests. Non-normal variables were assessed using the Mann-Whitney U test, while categorical variables were analysed with Chi-square tests. Statistical significance was set at $p \leq 0.05$.

Results

A total of 132 patients were screened for eligibility, of which 50 met the inclusion criteria and were randomized into the test (n = 33) and placebo (n = 17) groups. Seven participants dropped out (2 from the test group and 5 from the placebo group), leaving 43 participants for the final analysis. (Fig. 1) No adverse effects of the treatment were reported in any of the group. Baseline characteristics did not significantly differ between the two groups (Table 2).

Primary outcomes

No significant improvement in hematological parameters (Hb, RBC, PCV, MCH, MCHC, MCV, RDW) was observed in either group. (Table 3)

Secondary outcomes

Similarly, no significant changes were observed in thyroid function (T3, T4, TSH) between the groups. However, a trend towards improved red cell distribution width (RDW) and reduced TSH levels was noted in the test group, though these changes were not statistically significant. (Table 3)

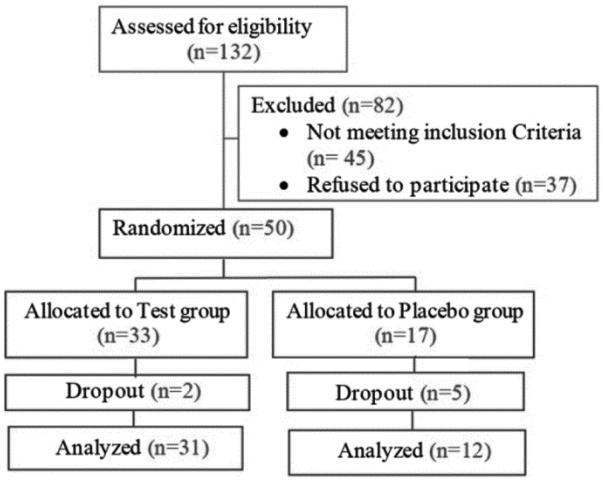

Fig. 1 — CONSORT diagram

Discussion

This study aimed to evaluate the therapeutic potential of *Majoon-e-Aarad Khurma* in improving anaemia-related outcomes in hypothyroid patients. The formulation was selected based on its alignment with Unani medicine principles, which emphasize treating cold-temperament diseases, such as hypothyroidism and anaemia, through remedies that restore balance. While *Majoon-e-Aarad Khurma* is not traditionally recognized for its hematinic properties, its rich composition of dry fruits and spices justifies its inclusion in this study.

The primary ingredient, *Phoenix dactylifera* (dates), has demonstrated significant hematopoietic potential in various studies. For instance, Onuh *et al*., 2012 found that date palm extracts significantly increased hemoglobin and red blood cell counts in Wistar rats[26]. Similarly, Sari *et al*., 2018 reported improved hemoglobin levels in adolescent girls supplemented with dates and iron[27].

Another key ingredient, *Piper longum*, has been traditionally used to stimulate liver function and

Table 2 — Baseline characteristics

Variables	Test group (n=31)	Placebo group (n=12)	p-value
Age, Mean ± SD	38.16±9.42	32.42±6.54	0.060*
Gender, n (%)			
Female	31 (72.1%)	12 (27.9%)	
Religion, n (%)			
Hindu	7 (63.6%)	4 (36.4%)	0.469**
Muslim	24 (75%)	8 (25%)	
Marital Status, n (%)			
Married	30 (71.4%)	12 (28.6%)	0.529**
Unmarried	1 (100%)	0 (0.0%)	
Family History, n (%)			
Positive	13 (72.2%)	5 (27.8%)	0.987**
Negative	18 (72%)	7 (28%)	
Diet, n (%)			
Vegetarian	1 (50%)	1 (50%)	0.476**
Mixed	30 (73.2%)	11 (26.8%)	
Duration of Hypothyroidism, Mean ± SD	5.40±3.76	7.22±4.98	0.20*
Dosage of Thyroxine Mean ± SD	67.74±38.83	61.42±33.51	0.60*
BMI, Mean ± SD	28.68±4.90	28.36±4.895	0.850*
Peripheral smear, n (%)			
NNA	25 (80.64%)	11 (91.66%)	0.380**
MHA	6 (19.35%)	1 (8.33%)	
Severity			**Total**
Mild (11-11.9 g/dL)	11 (35.48%)	7 (58.33%)	18 (41.86%)
Moderate (8-10.9 g/dL)	20 (64.51%)	5 (41.66%)	25 (58.13%)

p* Independent student-t test, p** Chi-square test, NNA: Normocytic Normochromic Anaemia, MHA: Microcytic Hypochromic Anaemia

Table 3 — Objective parameters

Variables	Test group (n=31)	Placebo group (n=12)	P-value
Hb (g/dL)			
Before	10.40±1.09	10.72±1.03	0.389[b]
After	10.49±1.20	10.78±1.30	0.498[b]
P-value	0.351[a]	0.833[a]	
RBC count (millions/cumm)	4.47±0.42	4.45±0.33	0.869[b]
Before	4.55±0.35	4.39±0.43	0.221[b]
After	0.137[a]	0.508[a]	
P-value			
PCV (%)			
Before	32.91±2.89	35.05±4.98	0.086[b]
After	33.72±3.82	33.51±3.71	0.870[b]
P-value	0.174[a]	0.130[a]	
MCHC (g/dL)			
Before	29.82±01.24	29.82±1.10	0.995[b]
After	30.01±1.06	30.42±1.27	0.296[b]
P-value	0.295[a]	**0.016[a]**	
MCH (pg)			
Before	24.67±10.04	24.31±2.53	0.905[b]
After	24.75±9.75	24.49±2.80	0.928[b]
P-value	0.970[a]	0.870[a]	
MCV (fl)			
Before	76.72±7.47	81.18±6.52	0.077[b]
After	76.74±7.45	77.35±11.36	0.838[b]
P-value	0.962[a]	0.235[a]	
RDW (fl)			
Before	45.75±3.78	45.33±3.27	0.738[b]
After	44.81±6.32	47.05±5.61	0.289[b]
P-value	0.247[a]	0.420[a]	
T_3 (ng/mL)			
Before	0.97±0.38	0.86±0.21	0.409[c]
After	1.003±0.37	0.91±0.20	0.745[c]
P-value	0.640[a]	0.096[a]	
T_4 (µg/dL)			
Before	9.13±2.47	8.86±2.19	0.898[c]
After	9.09±2.34	9.05±1.82	0.494[c]
P-value	0.898[a]	0.882[a]	
TSH (µL/mL)			
Before	4.26±5.30	3.10±1.89	0.957[c]
After	3.17±2.53	2.84±2.00	0.892[c]
P-value	0.268[a]	0.308[a]	

p[a] Paired t-test, p[b] Independent student-t test, p[c] Mann-Whitney U Test

improve blood production. It's use in Ayurvedic formulations like *Vajravatakamandura* has shown improvements in hematological parameters and symptomatic relief in anemic patients[28]. The formulation also included *Cocos nucifera* (coconut), which exhibits hematopoietic properties. A study by Rao *et al.* on rabbits fed coconut water showed improved hematological outcomes, making it a valuable addition[29].

Notably, *Vardhamana pippali rasayana* another Ayurvedic formulation, derived from the dried fruits of *Piper longum*, has alleviated symptoms of hypothyroidism and improved the thyroid profile[30]. Furthermore, *Zingiber officinale* (ginger) has been shown to significantly reduce Thyroid-Stimulating Hormone (TSH) levels and ameliorate symptoms of hypothyroidism[31]. Likewise, *Syzygium aromaticum* (clove oil) demonstrated an augmentation in thyroid functions upon administration in propylthiouracil (PTU)-induced hypothyroidism in Wistar rats[32].

Ayurvedic compounds such as *Kanchanar Gutika* and *CV-HFT01* tablets, which comprise spices including *Zingiber officinale*, *Piper longum*, and *Cinnamomum zeylanicum*, have shown efficacy in improving thyroid profiles alongside alleviating symptoms of hypothyroidism[33,34]. This suggests a probable potential synergistic effect in the components of *Majoon-e-Aarad Khurma*.

Despite these promising individual components, our study found no significant improvements in overall hematological parameters. Although the changes in hematological parameters were not statistically significant, a small trend towards improvement was observed in the test group. Specifically, the hemoglobin (Hb), RBC count, PCV, MCH, and MCHC values showed slight increase, and the RDW decreased which we expect in an improving case. In contrast, the placebo group exhibited a decline in RBC count, PCV, and MCV values, alongside an increase in RDW, which is often seen in anaemia associated with hypothyroidism[35]. However, these changes were minimal (primarily occurring in the first or second decimal place), we observe a stabilizing effect of *Majoon-e-Aarad Khurma* on hematological parameters. However, given the lack of statistical significance, these findings should be interpreted with caution, and they may not have clinical relevance in this study's short duration. Further studies with longer treatment durations with higher doses and larger sample sizes are necessary to explore these preliminary trends further.

As part of our study, peripheral smear analysis was conducted at the time of enrolment, revealing normocytic-normochromic anaemia as the most prevalent form among participants. This finding is consistent with existing literature, which also highlights normocytic-normochromic anaemia in hypothyroid patients[36-38]. While some studies have reported microcytic-hypochromic anaemia in subclinical hypothyroidism[39]. Regarding the demographic parameters, all participants in this study

were female, reflecting the higher prevalence of hypothyroidism and anaemia among women[34].

In terms of anaemia severity, our findings align with previous research, indicating that severe anaemia is rarely associated with hypothyroidism. Most participants exhibited mild to moderate anaemia, consistent with earlier findings. This pattern reinforces the observation that hypothyroidism more commonly presents with less severe forms of anaemia[40].

Limitations of the study

The present study has certain limitations. First, the treatment duration of 45 days may have been insufficient to observe meaningful changes in haematological parameters, considering the approximate lifespan of red blood cells. Second, the dose of *Majoon-e-Aarad Khurma* (10 g once daily) may have been inadequate to elicit a measurable therapeutic response. In addition, the study experienced higher attrition in the placebo group, largely due to loss to follow-up during the COVID-19 pandemic, which may have affected group comparability. The use of a 2:1 randomization ratio also resulted in a relatively smaller placebo group, thereby reducing effective sample size and potentially limiting statistical power. These methodological constraints may have affected the generalizability of the findings and should be considered while interpreting the results.

Conclusion

In the present study, *Majoon-e-Aarad Khurma* used as an adjunct therapy for 45 days did not show statistically significant improvement in haematological parameters or thyroid function compared with placebo in patients with anaemia associated with hypothyroidism. Although the formulation is traditionally regarded as a nutritive and temperamentally appropriate Unani preparation, its clinical benefit could not be established under the present study conditions. Further studies with larger sample size, longer duration, and more detailed evaluation of anaemia subtype and biochemical parameters are needed to better assess its therapeutic potential.

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Authors Contribution

The methodology, investigation, formal analysis, and writing of the original draft were carried out by FE. The study's conceptualization, validation, supervision were overseen by MAQ, US, SAZ and SK participated in case identification, data collection and review and editing of manuscript.

Ethical Approval

The study adhered to the principles of the Helsinki Declaration and was approved by the Institutional Ethics Committee (IEC No: NIUM/IEC/2019-20/001/Moal/01, dated 24.9.2020).

Informed Consent

Written informed consent was taken from each participant in their own language before randomization.

Conflict of Interest

Declared none.

AI Use Declaration

AI tools were used only for language enhancement and improvement of readability. All scientific content and interpretations are the original work of the authors.

Data Availability

The data that support the findings of this study are available from the corresponding author, [Faseeha Eram], on special request.

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