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Evaluation of Safety of Unani Pharmacopieal Majoon-e-Lana in Cases of Neurasthenia

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Abstract

Neurasthenia, referred to as Zof-e-Asaab in the Unani system of medicine, is a functional disorder characterized by generalized weakness of the nervous system. Individuals suffering from this condition commonly experience persistent fatigue, reduced physical and mental performance, low mood, irritability, disturbed sleep, and, in some cases, elevated blood pressure. Although various conventional treatment options are available for symptom management, no specific curative therapy has been established. Furthermore, long-term use of certain modern medications may be associated with undesirable adverse effects, highlighting the need for safer and more effective therapeutic alternatives. Unani medicine offers a holistic approach to health and emphasizes the use of natural formulations that have traditionally been considered safe and well tolerated. The present study was undertaken to evaluate the safety of the Unani pharmacopoeial formulation Majoon-e-Lana in patients diagnosed with neurasthenia (Zof-e-Asaab). Eligible participants were screened according to predefined diagnostic criteria before enrollment. Baseline clinical assessment was performed, and fasting blood samples were collected for laboratory investigations. Participants received Majoon-e-Lana at a dose of 5 g twice daily with plain water after meals for a treatment period of six weeks. To monitor the safety profile of the formulation, biochemical parameters, including liver function tests (LFTs) and kidney function tests (KFTs), were evaluated at baseline and after completion of the intervention. Clinical observations and laboratory findings were carefully analyzed throughout the study period. No serious adverse events or clinically significant abnormalities were observed during treatment. Based on these findings, Majoon-e-Lana appeared to be well tolerated and demonstrated a favorable safety profile, suggesting that it is safe for human consumption and may serve as a potential supportive therapeutic option for the management of neurasthenia.

Keywords: Neurasthenia, validation study, Zof-e-Asaab, clinical trial, unani pharmacopieal

INTRODUCTION

Neurasthenia (from the Ancient Greek neuron “nerve” and asthenès “weak”) is a term that was first used for a mechanical weakness of the nerves in 1829. Neurasthenia, commonly associated with chronic fatigue syndrome (CFS), is a disorder characterized by persistent and unexplained fatigue that is not relieved by rest and is often aggravated by even mild physical or mental activity. Patients frequently experience additional symptoms such as impaired concentration, dizziness, muscle pain, and disturbances in sleep [1]. The diagnosis is primarily based on clinical evaluation after excluding other medical conditions that may cause chronic fatigue. Although its exact cause remains unclear, research supports the recognition of this condition as a distinct clinical syndrome. The reported global prevalence ranges from 0.5% to 2.5%, with variations largely attributable to differences in diagnostic criteria and study populations. Neurasthenia is a historical term used to describe a

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condition marked by persistent fatigue and a sense of physical weakness in the absence of any identifiable organic or neurological disease. Individuals with this disorder often report subjective feelings of exhaustion, reduced energy, and generalized weakness. However, objective clinical examinations typically do not demonstrate true muscle weakness. Instead, muscle strength testing may reveal inconsistent effort or "give-way" weakness, a feature commonly associated with functional or non-organic disorders. In such cases, the reported fatigue usually reflects a sensation of tiredness, lack of motivation, or mental exhaustion rather than a measurable decline in muscle strength following repeated physical activity [2].

Neurasthenia is a state determined by the interaction between an inherited neurotic tendency and environmental stress. It is believed that social stress derived from work and living places in modern society makes it easy for people to suffer from neurasthenia. Neurasthenia is associated with considerable disablement in daily life. The ICD-10 defines neurasthenia as a condition in which individuals experience persistent and distressing fatigue after mental exertion or continuous sensations of physical weakness and exhaustion following relatively minor physical activity. These symptoms are often severe enough to interfere with daily functioning and overall quality of life [2]. Clinically, neurasthenia is always a functional diagnosis and is manifested by at least two symptoms out of the following associated symptoms: muscular aches and pains, dizziness, headaches, sleep disturbance, inability to relax, irritability, and dyspepsia. In many instances, "chronic fatigue syndrome" is preferred by clinicians and used to replace neurasthenia. Epidemiological studies indicated that this disease had wide ranges of incidence and frequency of major symptoms depending on ethnicity, lifestyle, and individual character [3].

UNANI CONCEPT

As per unani concept human body is comprised of Aza e Mufrada (simple organs, i.e., cells and tissues) and Aza e Murakkaba (Compound organs, i.e., organs and organ systems). A'asab (Nerves or nervous tissues) are categorized as Aza e Mufrada in Unani system of medicine.

The main functions of A'asab in the body according to Unani system of medicine was Harkat, i.e., sensory and motor functions of the body. Whenever either of these two or both functions is disturbed then the disease condition Ḍu'f A'ṣāb occurs. As per Unani medicine every organ of the body has a unique Mizaj or temperament, comparatively different from the temperament of other body organs and this Mizaj is in congruence to the natural needs. Mizaj of A'ṣāb is considered as Barid Yabis, i.e., Cold and Dry. An alteration / deviation in the Mizaj of A'ṣāb leads to the disturbance in the normal functioning of A'ṣāb, thereby affecting both sensory and motor functions of nerves [4].

Etiological Factors (Asbab-e-Marz)

Family History of Sar'a (Epilepsy), Ikhtinaq ur Reham (Hysteria), Junoon (Psychosis); Congenital anomalies, excessive physical or mental exertion or emotional stress, infectious diseases, Tap-e-Muharraqa (Hyperpyrexia), Nazla wabaiya (Epidemic Influenza); Chronic diseases, e.g., Tuberculosis, Cancer, Syphilis, Diabetes Mellitus, chronic gastritis, etc. are some of the important causes of neurasthenia. Other factors include excessive coitus or masturbation, excessive consumption of alcohol, tea, coffee and drug abuse besides neurogenic shock, accident, trauma, etc. may also cause Ḍu'f A'ṣāb [4].

Sign and Symptoms (Alamaat Marz)

Patients with general debility, weakness, low self-esteem, irritability, insomnia, fasciculation, headache, backache, dyspepsia, loss of appetite, constipation, mental stress, palpitation, pallor, body aches, tingling and numbness were considered as mentioned as sign and symptoms of Ḍu'f A'ṣāb in Unani literature and Diagnostic Criteria [CCMD-III diagnostic criteria]. Patients are required to have any three of five groups of persistent symptoms which include fatigue or weakness (Physical or Mental), irritability or worry, excitability, nervous pain, sleep disturbances and require the exclusion of all mood and anxiety disorders [5].

Study Rationale

At present, there is no definitive treatment available for neurasthenia, and management primarily focuses on relieving symptoms and improving patients' quality of life. In individuals with associated sleep disturbances, benzodiazepines are commonly prescribed because they help reduce anxiety, promote sleep initiation, and improve sleep maintenance. However, prolonged use of these medications may result in adverse effects such as sedation, tolerance, physical dependence, and withdrawal symptoms. Tricyclic antidepressants, including imipramine, have also been used to alleviate anxiety-related manifestations and certain symptoms of neurasthenia. Despite their therapeutic benefits, these agents are not considered first-line treatment due to their unfavorable side-effect profile and the potential for significant drug interactions. Given the limitations and safety concerns associated with currently available pharmacological therapies, there is a growing need to explore safer and more effective treatment options. Traditional systems of medicine, such as Unani medicine, may offer promising alternative therapeutic approaches that warrant further scientific evaluation for the management of neurasthenia. The Unani system of medicine adopts a holistic approach to the management of diseases and emphasizes the use of natural remedies that are generally regarded as safe and well tolerated. Neurasthenia, known as Ḍu'f A'ṣāb in Unani medicine, has been extensively described in classical Unani literature. Traditional Unani physicians have outlined its etiology, clinical manifestations, classification, and treatment strategies based on the underlying causes and nature of the disorder. Numerous Mufrad (single-drug) and Murakkab (compound) formulations possessing Muqawwi-e-A'ṣāb (nervine tonic) and Muharrik-e-A'ṣāb (nervine stimulant) properties have been recommended for strengthening the nervous system and alleviating the symptoms of Ḍu'f A'ṣāb. These formulations have been employed in clinical practice for centuries and are traditionally believed to be both effective and safe. However, despite their long-standing use, scientific evidence supporting their safety and therapeutic efficacy remains limited. Therefore, systematic clinical investigations are essential to validate these traditional formulations using modern scientific methods and to establish evidence-based data regarding their safety and effectiveness [6].

Majoon-e-Lana is a well-known pharmacopoeial formulation in the Unani system of medicine and has traditionally been prescribed for the management of Ḍu'f A'ṣāb (Neurasthenia). In addition to its use as a nervine tonic, it is also recommended for several neurological and musculoskeletal disorders, including hemiplegia, facial paralysis, tremors, arthralgia, and epilepsy. According to Unani principles, Majoon-e-Lana possesses a Haar (hot) Mizaj (temperament), which is considered therapeutically beneficial in conditions associated with a Barid (cold) temperament such as Ḍu'f A'ṣāb. Based on the fundamental Unani concept of Ilaj bil Zid (treatment by opposites), the formulation is believed to restore the altered temperament and improve the functional integrity of the nervous system. Owing to its long history of clinical use and its traditional reputation for safety and effectiveness, Majoon-e-Lana has gained considerable importance in Unani practice. However, despite its widespread use, scientific evidence supporting its therapeutic efficacy and safety remains limited. Therefore, the present clinical study was undertaken to systematically evaluate the efficacy and safety of Majoon-e-Lana in patients with Ḍu'f A'ṣāb (Neurasthenia) using modern scientific and clinical assessment parameters.

Study Objectives

To evaluate the safety of Unani Pharmacopoeial formulation Majoon-e-Lana in Ḍu'f A'ṣāb (Neurasthenia).

Overview of Study Design

The study was designed as an open-label, clinical trial in patients with Ḍu'f A'ṣāb (Neurasthenia). The patients were subjected to screening. Following the screening process, eligible participants were enrolled in the study and administered the Unani pharmacopoeial formulation *Majoon-e-Lana* at a dose of *5 g twice daily*, to be taken with plain water after meals. The treatment regimen was continued for a total duration of *six weeks,* during which participants were monitored regularly for treatment compliance and safety. The laboratory investigations were conducted at baseline and at the end of treatment. There is no clinical trial number and is not applicable [7].

MATERIAL AND METHODS

Selection Criteria

The patients of Ḍu‘f A‘ṣāb (Neurasthenia) attending OPD were selected for study, A detailed medical history was obtained from all participants, followed by a comprehensive physical examination to establish the clinical diagnosis of Ḍu‘f A‘ṣāb (Neurasthenia). Eligibility for participation was determined based on predefined inclusion and exclusion criteria. Only patients who fulfilled all the inclusion criteria and did not meet any of the exclusion criteria were enrolled in the study. After confirming eligibility, informed consent was obtained from each participant before their inclusion in the clinical trial.

Inclusion Criteria

Male and female patients aged 18–60 years who were clinically diagnosed with Ḍu‘f A‘ṣāb (Neurasthenia) according to the predefined diagnostic criteria were considered eligible for inclusion in the study.

Exclusion Criteria

Patients below the age of 18 and above the age of 60 years, having any systemic disease, chronic debilitating disease, T.B., Diabetes Mellitus, etc. were excluded from the study, etc. Patients with history of addiction (Alcohol, Drugs and, etc.) and known case of Carpal tunnel syndrome, herniated disc syndrome, peripheral nerve injury, any neuromuscular abnormalities, or junction disorders, Myasthenia gravis, Muscular disorders, Diabetic neuropathy, Autonomic neuropathies. Pregnant and lactating mothers were also excluded.

Patients with Ḍu‘f A‘ṣāb (Neurasthenia) attending OPD of the Institute were assessed for biochemical parameters. They were informed about the nature and objectives of the study and details of study related procedures. Information consent was obtained before enrolling into the study. The detailed history was recorded, and the patients were examined clinically to record the various signs and symptoms of Ḍu‘f A‘ṣāb (Neurasthenia). Blood samples were collected for biochemical investigations. The study drug was dispensed as per the schedule, and patients were instructed to take the medicine as per the protocol.

Study Drug Details

The study participants received the Unani pharmacopoeial formulation Majoon-e-Lana as the study drug. The formulation was administered orally in a semi-solid form at a dose of 3 g twice daily with water after meals (Table 1). The composition of the Unani pharmacopoeial formulation Majoon-e-Lana used in the present study is presented in Table 2.

Table 1. The following Unani pharmacopoeial formulation was used.

Study drug	Form	Route of administration	Dose	Frequency	Instructions
Majoon-e-Lana	Semi Solid	Oral	3 gm	Twice Daily	To be taken with water after meals.

To scientifically validate the safety of the Unani pharmacopoeial formulation Majoon-e-Lana, a clinical study was conducted involving 42 participants who were initially screened for Ḍu‘f A‘ṣāb (Neurasthenia) based on the predefined diagnostic criteria. Eligible participants received Majoon-e-Lana at a dose of 5 g twice daily, administered with plain water after meals. The treatment was continued for a period of six weeks. Clinical and laboratory assessments were performed at baseline and repeated at the end of the treatment period. Fasting blood samples were collected before the initiation of therapy and after six weeks to evaluate the safety profile of the formulation. Biochemical investigations included liver function tests (LFTs) and kidney function tests (KFTs), which were compared between baseline and post-treatment to detect any treatment-related changes [8–10].

Table 2. Composition of Majoon-e-Lana.

S.N.	Ingredients	Bptanical/scientific name	Part used	Quantity
1.	Azaraqi Mudabbar	*Strychnos nux-vomica* L	Seed	20 g
2.	Filfil Safaid	*Piper nigrum* L.	Fruit	10 g
3.	Filfil Siyah.	*Piper nigrum* L	Fruit	10 g
4.	Darchini.	*Cinnamomum zeylanicum* B	Inner stem bark	10 g
5.	Filfil Daraz	*Piper longum* L.	Fruit	10 g
6.	Jauzbuwa.	*Myristica fragrans* H	Endosperm	10 g
7.	Bisbasa	*Myristica fragrans* H.	Arillus	10 g
8.	Mastagi	*Pistacia lentisus* L.	Resin	10 g
9.	Sad Kufi	*Cyperus rotundus* L.	Rhizome	10 g
10.	Zanjabeel	*Zingiber officinale* R.	Rhizome	10 g
11.	Qaranful	*Syzygium aromaticum* M.	Flower bud	10 g
12.	Aamla	*Emblica officinalis* G.	Fruit	10 g
13.	Sumbul-ut-Teeb.	*Nardostachys jatamansi* D	Rhizome	10 g
14.	Heel Khurd	*Elettaria cardamomum* M.	Fruit	10 g
15.	Nankhwah	*Trachyspermum ammi* L.	Fruit	10 g
16.	Badiyan	*Foeniculum vulgare* M.	Fruit	10 g
17.	Zafran	*Crocus sativus* L.	Stamen & Stigma	10 g
18.	Sandal Safaid	*Santalum album* L.	Heart wood	10 g
19.	Ood-e-Balsan	*Balsamodendron Opobalsamum* K.	Wood	10 g
20.	Agar	*Aquilaria agallocha*	Heart wood	10 g
21.	Asal / Qand Safaid	Honey/Sugar		600 g

Ethics Approval Declaration

The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) of the Regional Research Institute of Unani Medicine, New Delhi, before the commencement of the study. All study procedures were conducted in accordance with the applicable ethical principles, relevant guidelines, and regulatory standards. Written informed consent was obtained from all participants prior to their enrolment in the study. As this investigation was conducted as an institutional clinical validation study, clinical trial registration was not applicable.

METHODOLOGY

Before enrolment, each participant was provided with a Participant Information Sheet (PIS) explaining the objectives, procedures, potential benefits, and possible risks associated with the study. Written informed consent was obtained from all participants before the initiation of any study-related procedures. Baseline demographic information detailed medical history, present illness, associated comorbidities, and concurrent medications were documented in the Case Report Form (CRF). A comprehensive general physical examination, along with a detailed systemic clinical assessment, was performed for every participant. Clinical features related to Ḍu‘f A‘ṣāb (Neurasthenia) were carefully evaluated and recorded in the CRF. Vital parameters, including blood pressure, pulse rate, body temperature, and respiratory rate, were measured and documented. In addition, fasting blood samples

were collected for laboratory investigations, including liver function tests (LFTs), kidney function tests (KFTs), blood glucose, and other relevant biochemical parameters, to assess the overall health status of the participants and to confirm their eligibility according to the predefined inclusion and exclusion criteria.

RESULTS

To evaluate the safety profile of the Unani pharmacopoeial formulation Majoon-e-Lana, fasting blood samples were collected from all participants at baseline and after completion of the six-week treatment period. Biochemical investigations, including liver function tests (LFTs) and kidney function tests (KFTs), were performed at both time points. The collected data were statistically analyzed using the paired Student's t-test to compare baseline and post-treatment values.

The analysis revealed a statistically significant reduction in serum glutamic oxaloacetic transaminase (SGOT) and alkaline phosphatase (ALP) ($p < 0.05$). A decrease was also observed in serum glutamic pyruvic transaminase (SGPT), total bilirubin, and serum creatinine; however, these changes were not statistically significant ($p > 0.05$). Conversely, a statistically significant increase in blood urea levels was noted ($p < 0.05$). Despite these variations, all biochemical parameters remained within their respective normal reference ranges throughout the study period (Table 3, Figure 1). Therefore, the observed changes were not considered clinically significant and did not indicate hepatic or renal toxicity.

No adverse events or serious adverse events were reported during treatment, suggesting that *Majoon-e-Lana* was well tolerated by the study participants and exhibited a favorable safety profile. As per the study protocol, any adverse event or serious adverse event, if encountered, would have been promptly documented and reported to the Institutional Ethics Committee within *24 hours* of its occurrence.

Table 3. Effect of Unani drug Majoon-e-Lana on liver and kidney function test in cases of neurasthenia.

Parameters group↓	SGOT	SGPT	*T. bilirubin*	ALP	Urea	Creatinine
Pre-Treatment	31.8462 ± 1.47701	30.0256 ± 1.601	0.7538 ± 0.37	104.5 ± 36.194	22.4564 ± 5.75	0.7079 ± 0.192
Post-Treatment	29.8974 ± 1.10867	26.4359 ± 9.366	0.5715 ± 0.199	98.38 ± 25.93	23.1795 ± 5.36	0.6436 ± 0.168

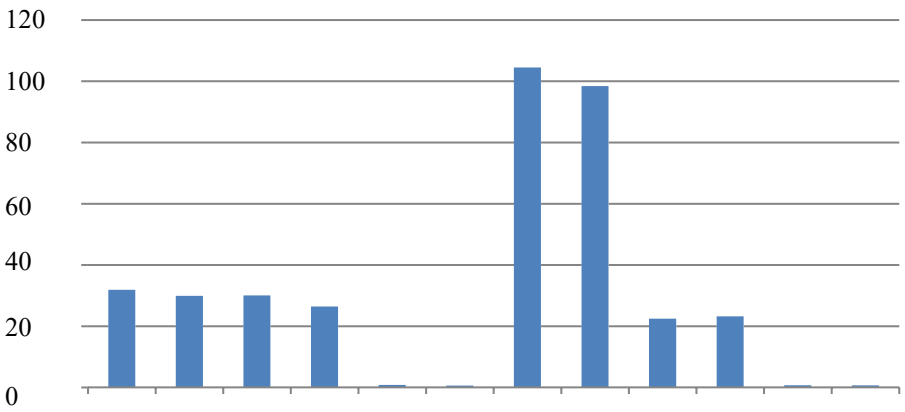

Figure 1. Graphical representation showing effect of Unani formulation on liver and kidney function test.

It was found that there was no abnormality in both the liver and kidney function test, therefore, it can be said that it is safe for human consumption.

CONCLUSION & DISCUSSION

It has been seen that no specific therapies are available for neurasthenia. Allopathic drugs have low incidence of side effects, but they may cause physical dependence and sedation. Thus, there is need for discovering novels and safe therapies for neurasthenia. It has been found that approaches of Unani medicine are considered natural and safe. Considering the need for safe and evidence-based therapies for Ḍu‘f A‘ṣāb (Neurasthenia), the present validation study was undertaken to assess the safety of the Unani pharmacopoeial formulation Majoon-e-Lana. After screening, eligible participants diagnosed with Neurasthenia were enrolled and treated with Majoon-e-Lana at a dose of 5 g twice daily, administered with plain water after meals for a period of six weeks. Clinical evaluation and laboratory investigations were performed at baseline and at the completion of the treatment period. Safety assessment was based on liver function tests (LFTs) and kidney function tests (KFTs). The results demonstrated that all biochemical parameters remained within their normal reference ranges throughout the study, and no adverse events or clinically significant toxic effects were observed. These findings indicate that Majoon-e-Lana was well tolerated and exhibited a favorable safety profile. Therefore, the formulation may be considered safe for human consumption and has the potential to serve as an alternative therapeutic option for the management of Ḍu‘f A‘ṣāb (Neurasthenia). However, further large-scale, randomized controlled studies are recommended to establish its long-term safety and therapeutic efficacy.

Author Contribution Declaration

Author contributed to conception, data collection, its analysis, and writing of this manuscript.

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Funding Declaration

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Ethical Statements

The study was started after getting ethical clearance. Informed consent was taken from each participant.

Conflict of Interest

There was no conflict of interest in this study. This manuscript has not been published or currently under review for publication.

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