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Research Article

A Novel Treatment for Scabies with Herbal Formulation: A Clinical Safety Assessment Study

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Abstract

Introduction: Scabies, known as Jarb in Unani medicine, is a parasitic infection caused by the mite *Sarcoptes scabiei* var. *Hominis*. It is characterized by intense itching, particularly noted by patients at night. In India, this disease affects over three million people, manifesting as papular or vesicular eruptions accompanied by pruritus. Unani physicians have developed comprehensive treatments for scabies, considering its causative factors and various types.

Methods: This study was conducted as an open-label, single-arm clinical trial involving 75 patients diagnosed with scabies with male female ration of 1:2.7. The primary objective was to assess the efficacy and safety of a compound Unani formulation. The test group received a Compound Unani formulation Irtifal Shahtra (*Fumaria indica* Pugsley) at a dose of 5 grams twice daily, Marham Kharish Jadeed (*Lawsonia inermis*) for topical application twice daily, and Aab-e-Barg-e-Neem (a decoction of Neem leaves) for washing the affected areas before applying Marham twice daily, for a duration of 15 days. Both subjective and objective parameters were evaluated before and after the treatment period.

Results: In this study, 94% patients reported a significant reduction in itching after using unani formulation for Scabies. Only 5% patients had mild itching at the end of the study. Regarding cure of the lesions, the reduction in mean values from before to after treatment indicates an improvement in skin lesions. P-value less than 0.05 indicate that the results are statistically significant. Objective parameters such as the skin scraping test, demonstrated a significant reduction ($p < 0.001$). Importantly, no adverse effects were observed with the treatment regimen, further highlighting its effectiveness in alleviating scabies symptoms.

Conclusion: This study highlights the safe and effective utilization of Unani formulations in treating one of the most distressing skin disease scabies, without any adverse effects.

Keywords: Scabies, Jarb, Irtifal shahtra, Barg neem, Marham Kharish Jadeed, Classical Pharmacopoeial formulations.

Abbreviations: DALYs, Disability Adjusted Life years; GBDL, Global Burden of Diseases; OPD, Outpatient-Department; RRIUM, Regional Research Institute of Unani Medicine; CBC; Complete blood count; LFT, Liver function Test; KFT Kidney Function test; SD, Standard Deviation, CI, confidence interval; USA, United states of America; CA

INTRODUCTION

Scabies is a parasitic infection caused by the mite *Sarcoptes scabiei*, an ectoparasite that resides in mammalian skin and is not visible to the naked eye. In India, its incidence varies from 13% to 59% in rural and urban areas. Globally, scabies contributes to 0.21% of Disability-Adjusted Life Years (DALYs) according to the Global Burden of Disease (GBD) report, with recent studies indicating a significant increase in cases.⁴

The prevalence of scabies in the general population is approximately 10%, with congested areas such as slums and jails posing a higher risk.¹⁴ Diagnosis relies on key symptoms, including severe itching, especially at night (known as "Kikka"), and the appearance of rashes such as small red papules, vesicles, or pustules, notably on the hands, finger webs, and thighs. This infection is highly

transmissible¹⁶. Complications of scabies include pyoderma, as well as renal and heart diseases.¹⁰ various factors such as "fasaad khoon" (morbidly of blood), hot and humid conditions, overcrowded and congested environments, and poor sanitation contribute to its transmission. Additionally, the nutritional status of individuals plays a significant role in the outbreak of this disease.¹⁵

The mites of scabies were first observed by the Arabian physician Abual Hasan Ahmad Ibn Muhammad Tabri. His observations are documented in his book "Mualajat al Buqratiyya." In this work, he describes these mites as parasites that bear a resemblance to the nits of lice and are the causative organisms of Jarb, which is the term used for scabies. Ibn Muhammad Tabri's pioneering observations laid the groundwork for understanding the aetiology and nature of scabies, contributing significantly

to the early understanding of this skin condition.^{7,18} As per Unani concept Pathophysiology (Maahiyat) of Jarb (Scabies) is as under:

Conversion of Blood (Dam) into abnormal humours:

This refers to the Conversion of Khilt-e-Dam (Blood) into Khilt-e-Sauda, or increased ratio of Khilt-e-Safra in the blood or when blood combined with Balgham-e-Shore called Fasad-e-Dam (Abnormal Blood). This abnormal blood becomes a breeding ground for harmful organisms referred to as Ajsam-e- Khabeesa or pathogenic Organisms. If these organisms persist in the skin without being expelled they can result in the disorder known as Jarb (Scabies).¹⁹

Weakness of expulsive power of skin: (Zuf-i-Quwwat Dafia), The skin normally has mechanisms to expel foreign particles or organisms. When this ability is weakened, it becomes easier for the mites to establish themselves and reproduce.

Blockage of skin Pores (Masamat -e-Jild Ka band Hona): Blocked pores prevent proper ventilation and drainage of the skin. This can lead to the retention of moisture and other substances, creating a favourable environment for the mites.

Increased viscosity of causative substance (Ghilzat-i-Madda): This refers to an increase in the thickness or stickiness of the substances present on the skin, possibly due to inflammation or other factors. Such changes can provide a medium for the mites to move and reproduce.

Accumulation of morbid matter (Kasrat-i-Madda): Morbid matter refers to abnormal or diseased substances that accumulate on the skin. The presence of such matter can serve as a food source for the mites and contribute to their proliferation.^{2,6,17}

The line of treatment for Jarb (Scabies) as proposed by Unani physicians includes Tanqiya-e-Khilt-e-Fasida (Evacuation of morbid humours) Tasfiya-i-Dam (Blood purification) Tartib-i Badan (Moistening of body) Mana-e-Ufoonat-e-Jild (Antiinfective) Musakkinat-e-Jild (Sedative for skin). Bathing and cleaning of lesions, Washing of clothing and cleaning of bedding, prevention of hot, salty, viciid and sweet things.

As far as the pharmacotherapy for Jarb (Scabies) is concerned a number of therapeutic measures are being proposed in conventional medicine but most of them have numerous side effects like nausea and vomiting, weakness, tremors, irritability, disorientation, neurotoxicity is noted in gamma benzene hexachloride 1% lotion or cream. Hence there is a need of alternative medicine that is safe and effective in Jarb. Unani physicians have recommended many simple as well as compound formulations for this problem which treats this disease by their Muhilil (resolvent), Jali (detergent), Dafa-e-Taffun (Disinfectant) and Mudamil-e-Qurooh (cicatrizaant) property. Among such compound formulations Itrifal shahtara, Marham Kharish Jadeed along with Aab -e- Barg -e- Neem regime was selected from unani pharmacopeia which has been used since antiquity for this disorder, but no scientific

data was available for its efficacy and safety. Hence the current study was designed.

METHODS:

The study was carried in Regional Research Institute of Unani Medicine (RRIUM), Srinagar, Jammu & Kashmir. This was an open labelled single-arm clinical trial with sample size of 75 patients. Subsequent to the institutional ethical committee approval, uncomplicated cases of scabies (Jarb) of either gender between 10-65 years with presence of Scabetic lesions (papules, vesicles and burrows) at classical sites (Inter-digital spaces etc), nocturnal pruritus, history of pruritus in family members, history of contact with the scabies patient and /or microscopic demonstration of mites, eggs or faecal pellets were selected. Patients with crusted or nodular scabies, diabetes mellitus, known allergy to any of the study medication, pregnancy and lactation, alcoholics or drug abusers were excluded.

The patients were advised 6g of Itrifal Shahtara, a semisolid unani pharmacopoeial formulation to be taken orally twice daily after meals, Marham Kharish Jadeed for smearing the affected areas twice daily and Aab-e-Barg-e-Neem (decoction of neem leaves) for washing of the affected area before applying Marham twice daily for 2 weeks.

Patients were followed up weekly. Investigations were done at baseline and at the end of the study. The drug efficacy was assessed on decrease in skin lesions, severity of pruritus and Skin scraping test. The assessment of pruritus was done by Likert scale in which Grade 0 indicated No pruritus, Grade-1 indicated Mild pruritus, Grade -2 indicated Moderate pruritus and Grade -3 indicated severe pruritus. Skin lesions were assessed on 0-3 scale based on the number of lesions in which Grade- 0 indicated No lesions, Grade- 1 indicated \geq to 10 lesions, Grade-2 indicated 11-49 lesions, and Grade 3 indicated more than 50 lesions. Skin scrapping test was done for demonstration of mites or their eggs or faecal pellets by light microscopy. Safety parameters were Haemogram, liver function test (LFT) and kidney function test (KFT).

Statistical Analysis:

The data is reported as means \pm SD, percentages (%) or 95% confidence intervals (95% CI). All tests were two-tailed, and the level of significance was set at $P \leq 0.5\%$. In order to compare the means of the study variables before and after the introduction of herbal formulation, a paired t-test with 95% CI of the means was used. If the t-test showed a difference for any variable studied, Pearson's correlation test was performed to check for possible intervening variables (co-variance) by the analysis of the coefficient of determination (r^2) and r 95% CI. All assumptions for the undertaking of parametric tests were checked and accounted for. The efficacy of intervention is presented in figures. The statistical package SPSS, version 21, for Windows (San Diego, CA, USA) was used in the analyses.

RESULTS:

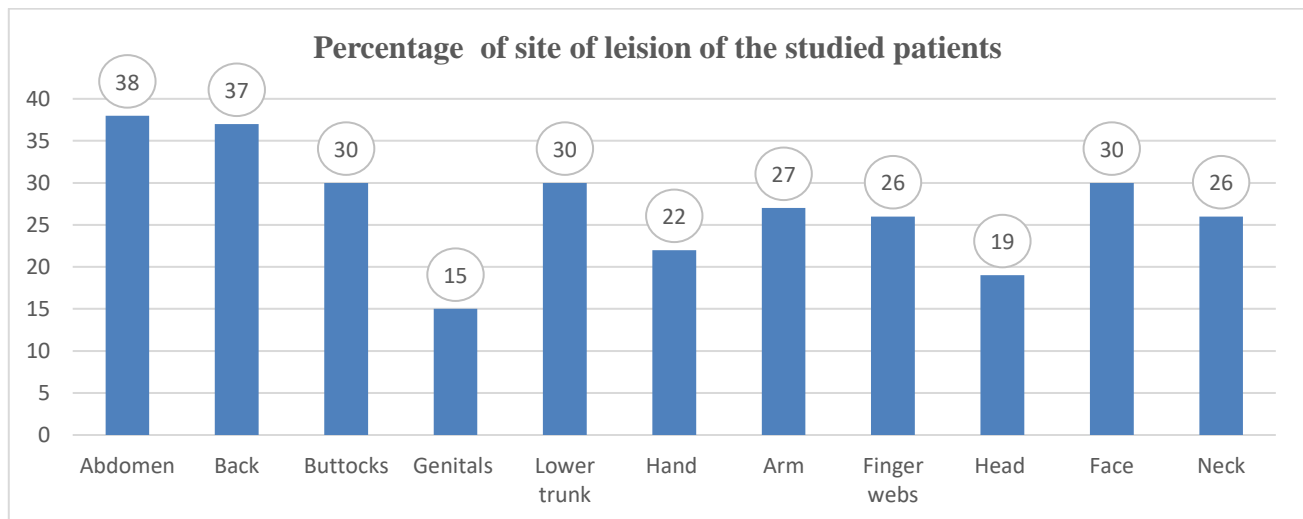


Figure 1: Shows the percentage of Site of lesion of registered patients:

This distribution indicates the most common sites of lesions for each body region, providing a clear overview of lesion. Maximum lesions were noticed on the

abdominal area followed by back. Buttocks, lower trunk and face were having the same severity followed by other areas shown in figure-1.

Table 1: shows the influence of disease and baseline characteristics for indicator subjects in each stratum Odds Ratios (OR) with 95% confidence intervals (CI) stratified by severity and age group

Variables	OR	95%CI	P-value
Age: >41	1	0.2662 to 2.4678	0.7115
<41	1.8		
Gender: Male	1	0.4342 to 1.8446	0.7635
Female	1.9		
Location: Rural	1	0.5184 to 2.0865	0.9121
Urban (slum)	1.1		
Severity: Mild	1	0.4273 to 12.036	0.02
Moderate	11.3		
Severe	17.3		
Income: Middle income	1	0.3581 to 2.7297	0.9824
High income	0.9886		
Occupation: House hold	2.0156	0.3179 to 12.7782	0.4569
Working	1		

75 patients of known cases who completed the study were evaluated for efficacy for the proposed herbal intervention. The indicators of the studied patients had a mean age of 35 years. It has been observed that the patients < 41 years were more prevalent to the disease and are female indicators than males. The odd ratio reported 1.9:1. The prevalence of the patients belonged to the urban (slum) area was little high here probably because of likely due to congested living conditions and poor hygiene. The severity of the disease was high

followed with moderate than mild and was statistically significant at the level of 0.05 significance. Middle-income group was more affected compared to the higher-income group. Middle-income groups were more affected, possibly due to factors not as severe as those affecting the urban slum population. Stagnant subjects were more prone to the disease than active subjects as the most of the studied subjects were house holders. The prevalence in housewives was more than working one (See Table 1).

Table 2: shows the comparison of the considered parameters (Lesions which were considered as typical for scabies are marked with) before and after the intervention.

Parameter	Assessment	Mean	Std. Deviation	95% Confidence Interval of the Difference		t-value	P-value
				L	U		
Burrows	Before treatment	4.56	10.874	1.473	5.114	3.604	< 0.05
	After treatment	1.27	4.332				
Papules	Before treatment	13.77	13.611	8.293	14.080	7.704	< 0.05
	After treatment	2.59	3.413				
Vesicles	Before treatment	7.81	7.663	4.805	7.542	8.987	< 0.05
	After treatment	1.64	3.364				
Pustules	Before treatment	2.27	9.142	-0.027	3.867	1.964	< 0.05
	After treatment	0.35	1.664				
Skin Scraping Test (SST)	Before treatment	0.20	0.403	0.078	0.269	3.617	< 0.05
	After treatment	0.03	0.162				

Type of lesion: The Table-2 displays the average values (means) and the spread (standard deviation) of skin lesion measurements before and after the treatment for different lesion types. The reduction in mean values from before to after treatment indicates an improvement in skin lesions. P-value less than 0.05 indicate that the results are statistically significant, meaning observed changes are unlikely to be due to chance. The significant P-value ($P < 0.05$) in the skin scraping test suggests a meaningful improvement due to the treatment. The treatment administered over two weeks has shown promising results, as indicated by the significant changes

in lesion measurements. The decrease in lesions indicate that the drug effectively improved the condition of skin lesions from baseline upto 14 days of treatment(Fig-1).The mean values and the statistical significance ($P < 0.05$) of the skin scraping test corroborate these findings, further validating the effectiveness of the treatment.

Grade of Lesions: The recruited patients were having mean lesions from 3-14. During the intervention the grade of lesion decreased significantly P-value < 0.05 in all respects. Fig-2

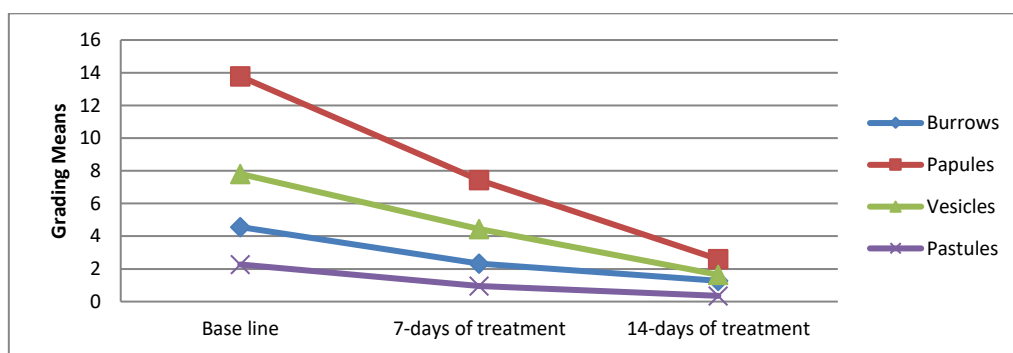


Figure 2: Shows the improvement of skin lesion during intervention

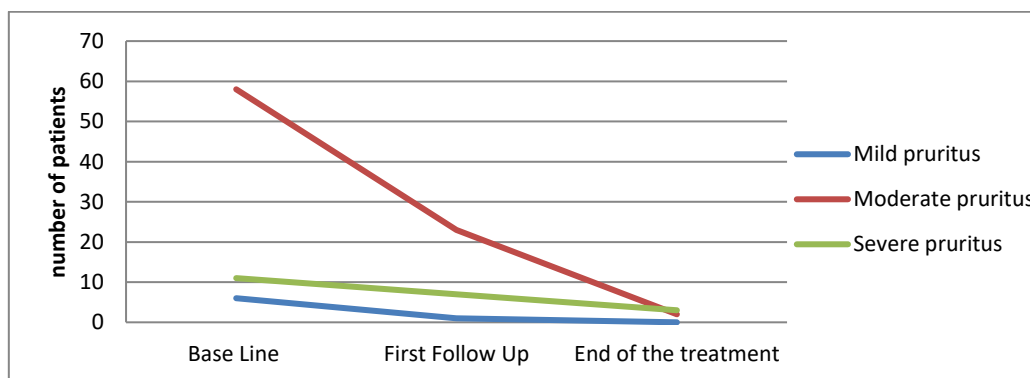


Figure 3: Shows the improvement of pruritus during intervention

Itching Severity Score:

At the baseline of the study, patients experienced pruritus ranging from mild to severe. During the intervention, the symptoms of pruritus decreased significantly. By the end of the study, 94% of the patients reported complete relief from pruritus, while only 5% noticed mild itching. These outcomes are illustrated in Fig-3

Mizaj(Temperament Evaluation):

When comparing the temperaments of the patients, it was observed that out of 75 patients, 57.3% had a phlegmatic (balghami) temperament, followed by 34.6%

with a bilious (Safravi) temperament, and 8% with a melancholic (Damvi) temperament. None of the patients exhibited a melancholic (Saudavi) temperament.

Safety evaluation:

The efficacy/safety evaluation has mainly been based on objective clinical features, findings and tests. Laboratory investigation including biochemistry and pathology investigations were taken into account to visualize any change during the intervention of proposed herbal regime. There were no significant results in the pathological and biochemistry of blood of the patients or any change in the urine after the therapy.

Table 3: shows biochemistry analysis of safety parameters

Biochemistry Assessment		Mean	Std. Deviation	95% CI of difference		t-value	p-value
				L	U		
Bilirubin (mg/dL)	Before Treatment	0.804	0.2986	-0.0196	0.1574	1.552	0.125
	After Treatment	0.735	0.2625				
SGOT (U/L)	Before Treatment	26.676	9.4493	-2.6204	2.6961	0.028	0.977
	After Treatment	26.638	12.4492				
SGPT (U/L)	Before Treatment	26.616	12.9146	-2.3521	3.1548	0.291	0.772
	After Treatment	26.215	14.1879				
S. Alkaline Phosphatase (U/L)	Before Treatment	84.850	30.9740	-4.7371	12.0939	0.871	0.387
	After Treatment	81.172	33.6262				
Creatinine (mg/dL)	Before Treatment	0.850	0.1455	-0.0171	0.0576	1.081	0.283
	After Treatment	0.830	0.1568				
Blood Urea (mg/dL)	Before Treatment	24.67	6.895	0.6650	3.6966	2.868	0.005
	After Treatment	22.485	6.0242				
Uric Acid (mg/dL)	Before Treatment	5.962	8.3513	-1.0229	2.7527	0.913	0.364
	After Treatment	5.097	1.2301				
Pus cell	Before Treatment	1.35	2.057	0.029	1.187	2.094	0.040
	After Treatment	0.74	1.325				
RBC	Before Treatment	0.05	0.281	-0.118	0.091	-0.257	0.798
	After Treatment	0.07	0.344				
Cl	Before Treatment	0.23	0.562	-0.020	0.290	1.738	0.086
	After Treatment	0.09	0.338				
Skin scrapping test	Before Treatment	1.81	0.394	-0.264	-0.087	-3.944	0.000
	After Treatment	1.99	0.116				

Table 4: shows pathology analysis of safety parameters

Pathological Assessment		Mean	Std. Deviation	95% CI of difference		t-value	p-value
				L	U		
Haemoglobin	Before Treatment	11.453	1.5693	-0.3149	0.3500	0.105	0.916
	After Treatment	11.435	1.6607				
TLC	Before Treatment	6578.38	1611.200	-263.390	482.309	0.585	0.560
	After Treatment	6468.92	1463.803				
Neutrophill	Before Treatment	61.96	5.612	-0.744	2.636	1.116	0.268
	After Treatment	61.01	6.830				
Lymphocyte	Before Treatment	41.41	54.545	-7.144	17.549	0.840	0.404
	After Treatment	36.20	6.752				
Eiosinophil	Before Treatment	1.80	0.721	-0.087	0.384	1.259	0.212
	After Treatment	1.65	0.671				
Monocyte	Before Treatment	1.14	0.728	-0.255	0.227	-0.112	0.911
	After Treatment	1.15	0.806				
Basophil	Before Treatment	0.00	0.000	-0.041	0.014	-1.000	0.321
	After Treatment	0.01	0.117				
ESR 1st Hr	Before Treatment	13.97	10.922	-3.746	1.881	-0.661	0.511
	After Treatment	14.91	11.355				
ESR 2nd Hr	Before Treatment	26.04	16.953	-5.433	2.704	-0.669	0.506
	After Treatment	27.41	18.386				

DISCUSSION:

Scabies, a neglected tropical disease prevalent in many low- and middle-income countries, is a skin condition characterized by intense itching, especially at night. It is caused by parasitic mites that burrow into the skin, triggering itching and a rash. Interestingly, the itching and rash are reactions to the excretions left behind by the mites in their burrows.¹⁸

Globally, around 200 million people suffer from this distressing affliction. The severe itching often leads to scratching, breaking the skin's protective barrier and resulting in various complications such as cellulites, abscesses, and, in rare cases, life-threatening renal failure.⁴

As per unani physicians the condition is basically due to fasade e-khoon (morbidly of blood) which is due to accumulation of fasid madda((impurities or toxins) in the blood ³.The cause of accumulation of this fasad e-madda in the body are many which includes polluted environment, wrong dietary habits (use of junk food), sedentary life style and excessive stress by which toxins get accumulated in the body. The body has a natural property to clear itself from these toxins, but when these impurities or toxins become excess, they began to affect the human body in a negative way. This is the basis of unani medicine to treat various types of skin diseases including scabies. These toxins also weaken the immune

system. The medicines used in our study like Itrifali shahtra and Barg neem (locally) are known blood purifiers used in Unani medicine which are indicated for purification of blood by removing the toxins and toxic metabolites by way of either neutralizing the effect of toxins or extract them from the body as these drugs are bitter in taste and have detergent, laxative and irrigator properties.^{10,17} These also act as tonic for vital organs especially liver. They restore the normal viscosity of blood by their moderate heat, cold, dry and wet properties. They also enhance the defensive mechanism and prevent the body from toxins,¹⁶ these drugs enhance the bowl moment and thus clean the body. ^{6,12} the main ingredient of our pharmacopoeial formulation Shahtra (*fumaria indica Pugsley*) has the properties of anti-helminthic, chologogus, diuretic, laxative and tonic properties, it strengths the liver as well. The other herb i.e is Neem (*Azadiracta indica*) which was used locally in our study is a most important detoxificant herb and is widely used for its antiseptic and antimicrobial properties which destroys the mite on the scabitic skin and also hinders its proliferation. It also causes the detoxification of blood as well.^{8,9}

As per conventional medicine the *Sarcoptes scabiei* mite, which causes scabies, makes certain proteins called Scabies Mite Inactivated Protease Paralogues (SMIPPs) and Serpins (Scabies mite serine protease inhibitors). These proteins stop the body's immune system from

working properly and help bacteria grow, making it harder for the body to get rid of the mites.²⁰The ingredients in our test drug exhibit immunomodulator properties by various mechanisms like by inhabiting growth T-lymphocyte, antibody production, inhibiting nitric oxide production and enhancing the expression of angiogenesis cytokines.^{21,22,23,24,25} Thus by enhancing immunity helps the body to get rid of the problem.

Our findings on lesion distribution were similar to findings from other trials²¹. It has to be taken into account that scabies typical lesions were a diagnostic criterion, thus predetermining the lesion distribution to a certain extent.

Strengths and limitations: the present study was first of its kind in Kashmir valley. It has some limitations as well. Firstly, the study was done on one type of population who live under same environment i.e Kashmir where the weather conditions are diverse in different seasons of the year. Moreover, the quality of life of the patients was not calculated in this study.

Future directions: In future the study may be done on different types of population groups living in different environmental conditions and to see the effect of the drug. Also Quality of life questionnaire may be including in future studies.

CONCLUSION:

In this clinical trial, participants who received an herbal therapy for scabies, administered both orally and topically, were more likely to be cured after two weeks. The benefits observed were modest, yet the overall effectiveness was not up to the expected and it was observed that it can give significant results only if the duration of treatment is enhanced to 4weeks.This suggests that the herbal formulation offers a comprehensive, safe, and economical treatment option only after increased the duration of treatment. As this is the first study of its kind, it is proposed that the duration of the treatment may be increased for assessing the effectiveness of the treatment. Further multi-centric clinical trials with larger sample sizes and double-blind allocation are necessary to generalize the efficacy of these herbal regimens.

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Ethics approval: N/A

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Author Contributions: All authors have equal contribution in the preparation of manuscript and compilation.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study and approval was taken before the clinical trial. (CTRI No: CTRI/2015/02/005527)

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