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ISSN 2321 - 6328

## Research Article

### **THERAPEUTIC EVALUATION OF ZIMAD-E-JARB IN JARB (SCABIES): A SINGLE BLIND RANDOMIZED CONTROLLED STUDY**

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Article Received on: 07/08/16 Accepted on: 09/10/16

**DOI: 10.7897/2321-6328.04540**

#### **ABSTRACT**

Scabies is a contagious skin disease, caused by *Sarcoptes scabiei* which affects around 300 million populations every year globally affecting mostly the children; but can occur in any age group and the incidence is similar in both sexes. The present clinical trial was designed to evaluate the efficacy of Zimad-e-Jarb in the management of Jarb on scientific parameters. It was a single blind randomized controlled study and was conducted on 30 patients of Jarb at National Institute of Unani Medicine, Bangalore. Participants fulfilling the inclusion criteria were included in the study, and were randomly allocated into Group A (n=20) and group B (n=10). Zimad-e-Jarb and 5% Permethrin lotion was given to the Group A and group B for 7 days and one day respectively as locally. Assessments were carried out on subjective & objective parameters weekly three times using arbitrary scale and VAS (pruritus) respectively. The result was analyzed statistically and both the drugs had significant effect on objective parameters (p<0.01). However control drug has shown more pronounced effect than test drug and no side effect was observed during and after the study. The study revealed that Zimad-e-Jarb is effective in Jarb in terms of itching, erythema, papules and number of lesions without any side effect. Therefore, it may be concluded that the test drug is safe & effective in management of Jarb.

**Key word:** Jarb; Scabies; Zimad-e-Jarb; Unani Formulation

#### **INTRODUCTION**

Scabies is universal throughout the world infesting around 300 million people each year.<sup>1</sup> It is endemic in many tropical and subtropical areas.<sup>2</sup> In India, the incidence in any Dermatology outpatient clinic varies from 10 to 30% of all cases with a seasonal prevalence and higher incidence in months of the winter season.<sup>3</sup>

Jarb (Scabies) is a well known dermatological disorder since Greco-Arabic period characterized by itching and eruptions. Ancient Unani scholars like Rabban Al Tabri, Sabit bin Qurah, Razi, Majoosi, Ibne Sina and others has mentioned the detailed description of Jarb in their treatises. The famous Arab physician Ahmad bin Mohammad Tabri firstly described Deedan-e-Jarb (scabies mite) as the actual pathogenic organism of Jarb which resembles Sanman (teeth). These organisms travel from one eruption to another leaving behind minute line till the energy in organism lasts.<sup>4,5</sup>

Jarb is synonymous to scabies which is a contagious skin disease produced by adult female mites, *Sarcoptes scabiei* that harbours mainly on the finger web spaces, the flexor aspects of the wrist, the nipple of the woman and genital area<sup>5</sup> which appear as fine, tortuous "S" shaped blackish threads of a few mm length,<sup>3,4,6,7</sup> and is transmitted through skin to skin contact and sexual transmission is also common, but non sexual transmission occurs by shared bedding, towel, clothing etc in family members.<sup>1,8,9,10</sup> Scabies occurs equally in both sexes and in all age groups, but the incidence is higher in children younger than 2 years of age. The papular pruritic eruption resulting from hypersensitivity reaction to the mites and its products<sup>11</sup>

mostly manifest around the abdomen, the lower portion of the buttocks, the axillary folds, and the elbows. As such there is no life threatening complication, however if not treated properly, may lead to eczematization, commonly in infants and young children, as well as secondary infections such as contact dermatitis and urticaria.

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 noticed in gamma benzene hexachloride 1% lotion or cream. Hence, there is dire need of alternative herbal therapies that are safe and effective in Jarb.

By the principles of treatment in Unani medicine, topical application has been preferred over other modalities in the treatment of Jarb and numerous Tila and Zimad are mentioned in classical text for its treatment. Unani physician have treated Jarb with the drugs that possess Muhallil (resolvent), Jali (detergent), Dafa-e-Ta'ffun (disinfectant), and Mundammil-e-Qurooh (cicatrizant) properties such as Tamarindus indica,<sup>12</sup> Gandhak Aamla Saar (sulphur); Neela Thotha (Copper sulphate); Kameela (*Mallotus philipensis*); Mudar-e-Sang<sup>13,14</sup>. Keeping these medicinal properties in consideration, Zimad-e-Jarb was selected for the study from Hamdard Pharmacopeia of Eastern medicine, as this formulation is endowed with the above mentioned properties. Despite Zimad-e-Jarb having been used since antiquity, it is yet to be explored on recent scientific parameters and as such no scientific data is available for its efficacy and safety. Hence, the clinical trial entitled "Therapeutic evaluation of Zimad-e-Jarb in Jarb (Scabies)-A single blind randomized controlled study" with the objective of

comparing the safety and efficacy of Unani formulation in the management of Jarb on scientific parameters.

## MATERIALS & METHODS

The present study was conducted at National institute of Unani medicine Hospital, Bangalore, from December 2013 to January 2015. The ethical clearance was obtained from Institutional Ethics Committee; then study was started by enrolling clinically diagnosed cases of Jarb (scabies) fulfilling the inclusion criteria were randomly allocated into group A and group B by using computer generated table. A total number of 36 patients were screened; 2 patients did not fulfill inclusion criteria, and were excluded from the study. Remaining 34 patients were randomly allocated into group A and group B; 4 patients from group A lost to follow up, and 30 patients (20 in group A and 10 in group B) took the complete course of treatment (Figure 1). The inclusion criteria were participants of 12 to 60 years of age of both sex, and willing to give informed consent. Exclusion criteria were patients below 12 years and above 60 years of age, terminal medical conditions such as cancer, any severe systemic illness, pregnant and lactating women, and patient who fail to follow up the protocol. Patients fulfilling the inclusion criteria were provided with an information sheet having details concerning the nature of study, the drug to be used, methods of treatment, and were given sufficient time to go through the contents of the informed consent form. Certain investigations were done with an aim to exclude the patients with pathological conditions mentioned under the exclusion criteria such as Haemogram, Random Blood Sugar, Blood Urea, Serum Creatinine, SGOT, SGPT, and Serum Bilirubin to exclude the secondary infections.

### Test Formulation<sup>13, 14</sup>

**Group A:** The ingredients of Zimd-e-Jarb are Gandhak Amla Saar (sulphur); Neela Thotha (Copper sulphate); Kameela (Mallotus philipensis); Mudar-e-Sang (litharge), and Roghan-e-Zard (Ghee). These drugs were procured from a registered herbalist, Bangalore and their identification was established by the Department of Pharmacy and Moalajat, NIUM. All the ingredients except Rogan-e-Zard were taken in equal quantity and pulverized to render the fine powder. Rogan-e-Zard in three

fold amount of the total weight of rest ingredients was heated to mix the fine powder of drugs for preparing Zimad-e-Jarb. Patients were advised to apply the same on whole body below neck daily for seven days.

### Group B: Standard Drug<sup>15</sup>

5% Permethrin (lotion) was procured from local drug store with the brand name of Permite manufactured by Galderma India Pvt. Ltd. Patients were advised to apply the same below neck on whole body only once.

### Efficacy Assessment

Scabies patients were categorized into either having: Mild infestation (less than three sites) scored as 1; Moderate (if lesion is more than 3 but less than 6 sites) was scored as 2, and Severe (if lesion is more than 6 sites) was scored as 3. The efficacy of Jarb in test and control groups for erythema and papules were assessed using 4 point grading scale. The objective parameter was assessed counting number of scabies lesions and assigned a score of 0-3, as: 0 = free of lesions (no scabies), 1= 10 or fewer lesions (mild), 2= 11- 49 lesions (moderate), and 3= 50 or more lesions (severe). The objective assessment of pruritus was done on a scale of 0 to 10 using visual analogue scale (VAS) score.<sup>16</sup> Duration of treatment was 7 days with the follow-up at 7<sup>th</sup>, 14<sup>th</sup>, and 21<sup>st</sup> days from onset of the treatment. No apparent side effect was observed during the course of clinical trial.

### Statistical Analysis

Friedman test was used for within group analysis; Kruskal-Wallis test with Dunn's Pair comparison test was applied for between group analysis, and Chi Square test was used to analyze qualitative data using Instat Graph Pad software. Difference in the treatment groups was considered significant at  $p < 0.05$ .

## RESULTS

Demographic data for both test and control groups has been depicted in Table 1. Effects of Zimad e Jarb in the test and control groups were assessed using Friedman test and Kruskal Wallis with Dunn's Pair comparison tests on pruritus and number of lesions (Table 2). Chi Square test was applied to see the outcomes of the study on reduction of erythema, and papules (Table 3, 4 & 5).

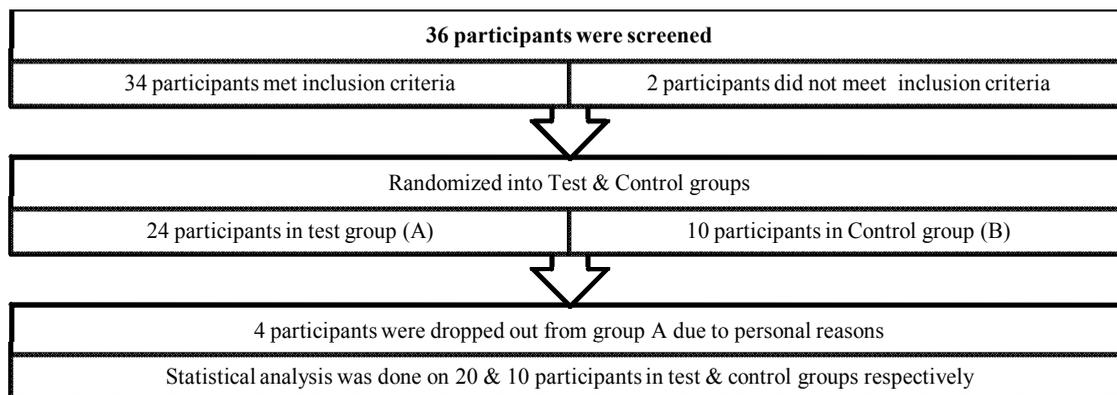


Figure 1: Flow Chart of Study Participants

**Table 1: Demographic Data**

Attributes	Test (n=20)	Control (n=10)
Age		
10-20	7	3
21-30	7	1
31-40	3	2
41-50	1	1
51-60	2	3
Gender		
Male	15	5
Female	6	4
Diet		
Mixed	18	2
Veg	8	2
SES		
I	0	0
II	0	0
III	5	2
IV	5	5
V	10	3

SES: socio economic status (Kuppaswamy 2007)

**Table 2: Effect of Zimad e Jarb on VAS Scores in Itching of Scabies Patients**

	Test	Control
Before Treatment	7.9±0.2039	7.6±0.2667
After Treatment	2.1±0.3457 <sup>a,b</sup>	1.8±0.4163 <sup>a</sup>
F1	0.9±0.3236 <sup>a,b</sup>	0.7±0.3000 <sup>a,b</sup>
F2	0.85±0.3424 <sup>a,b</sup>	0.6±0.2667 <sup>a,b</sup>

Test used: Friedman Kruskal-wallis Test with Dunn's Pair comparison Test; a-p<0.05 with respect to BTT; b-p<0.01 with respect to BTC; BTC=Before Treatment Control; BTT= Before Treatment Test

**Table 3: Effect of Zimad-e-Jarb on Number of Lesions of Scabies Patients**

	Test	Control
Before Treatment	2.85±0.8192	2.8±0.1333
After Treatment	0.7±0.1638 <sup>a,d</sup>	0.5±0.2236 <sup>b,c</sup>
F1	0.3±0.1469 <sup>a,d</sup>	0.2±0.2000 <sup>b,d</sup>
F2	0.3±0.1469 <sup>a,d</sup>	0.2±0.2000 <sup>b,d</sup>

Test used: Friedman Kruskal-wallis Test with Dunn's Pair comparison Test; a - p<0.05 with respect to BTT; b -p<0.01 with respect to BTT; c - p<0.05 with respect to BTC; d - p<0.01 with respect to BTC; BTC=Before Treatment Control; BTT= Before Treatment Test

**Table 4: Effect of Zimad-e-Jarb on Erythema**

Group	Mild	Moderate	Severe	P value
Before Treatment				
Test	0	4	16	0.5000
Control	0	2	8	
After Treatment				
Test	13	4	0	0.2109
Control	7	0	0	
Fallow up 1				
Test	7	3	0	0.3033
Control	4	0	0	
Fallow up 2				
Test	7	3	0	0.3033
Control	4	0	0	
Before and After comparison				
Before Treatment Test	0	4	16	0.0001**
After Treatment test	7	3	0	
Before treatment Control				
Before treatment Control	0	2	8	0.0009**
After Treatment Control	4	0	0	

Test used: Chi Square test; \* =p<0.05; \*\*=p<0.01

**Table 5: Effect of Zimad-e-Jarb on Papules**

Group	Mild	Moderate	Severe	P value
Before Treatment				
Test	0	10	10	0.5000
Control	0	5	5	
After Treatment				
Test	10	2	0	0.3424

Control	3	2	0	
Fallow up 1				
Test	3	2	0	0.3821
Control	2	2	0	
Fallow up 2				
Test	3	2	0	0.3821
Control	2	2	0	
<b>Before and After comparison</b>				
Before Treatment Test	0	10	10	0.0007**
After Treatment test	3	2	0	
Before treatment Control	0	5	5	0.0302*
After Treatment Control	2	2	0	

Test used: Chi Square test; \* = $p < 0.05$ ; \*\*= $p < 0.01$

## DISCUSSION

Maximum patients were found to be in the age group of 10-20 years which reveals that Jarb is more prevalent in teen agers contrary to the previous studies delineating the higher prevalence of scabies in school going children. On the other hand, Ali S M et al<sup>17</sup> reported that it is higher in teen agers asserting the current data. Out of 30 participants, 21(70%) were male and 9 (30%) were female patients. This study suggested male preponderance (Table-2) which is in conformity with the findings of Ali S M et al<sup>18</sup> Noor Ursani M, Baloch G H,<sup>19</sup> Khan I, Yasmin R,<sup>20</sup> Sharquie KE,<sup>21</sup> Das S, and Chatterjee T et al.<sup>22</sup> Out of 30 patients, 26 (86.66%) patients were non vegetarian and 4(13.33%) patients were vegetarian. Association of dietary habit with scabies has not yet been studied comprehensively, and hence a particular type of diet does not seem to have any casual relationship with scabies. However, according to Unani Medicine, dietary factors are believed to play important role in pathogenesis of Jarb. Dietary items possessing Haar Mizaj (hot temperament) such as salty and bitter edibles, garlic and onion, and excess use of sweetened materials play important role in causation of the disease.<sup>5, 23</sup>

The highest incidence 13 (43.33%) was observed in lower (V) class followed by 10 (33.33%) and 7 (23.33%) patients from upper lower (IV) and lower middle (III) class respectively. These data suggest that lower class and upper lower class people are more affected with disease which is in conformity with the finding of Rotti S B et al<sup>24</sup> asserting Unani literature that lower class people or people with low socio economic status with unhygienic life style have more incidences of scabies.<sup>25, 26</sup>

As for as Family history is concerned, 25 (83.33%) patients have positive family history while 5 (16.66%) patients did not have family history. This finding is in accordance to description of Unani description as observed by Das S, Chatterjee T et al.<sup>22</sup> In this study, 25 (83.33%) patients were belonged to urban area and 5 (16.66%) were from the rural area. It inferred that Jarb is directly related to the overcrowded areas with least sanitation care and low socio economic strata.

The outcomes of the study were assessed on parameters of itching, and erythema, papules and reduction in number of lesions. The graded affect of Zimad-e-Jarb versus Permethrin was found to be similar between the two groups at any assessment interval ( $p > 0.05$ ) from the baseline in terms of erythema and papules. Thus, it may be inferred that the two treatments are equally effective on subsiding the erythema and papule, although Zimad-e-Jarb showed better reduction in erythema and papule than the control drug. As far as the improvement in itching is concerned, it significantly reduced ( $p < 0.01$ ) from baseline. On inter group comparison, the result was also found significant ( $p < 0.05$ ) showing more pronounced effect than test drug; although both drugs are effective in reducing VAS itch scores for the treatment duration. The improvement in itching may be attributed to the Dafa-e-ta' affun (disinfectant) action of Gandhak, Tutiya Sabz and Kameela and Musakkin

(soothing) property of Murdar Sang. These finding are in concordance with the description made by Ibne Sina, Akbar Arzani, Azam Khan and Najmul Ghani.<sup>5,13, 27,28,29,30</sup>

The number of lesions significantly reduced ( $p < 0.01$ ) from the baseline data. On inter group comparison, the result was significant ( $p < 0.01$ ) with respect to baselines of test drugs establishing more pronounced effect than the test drug; although both the drugs are effective in reducing the number of lesion scores. This response of Zimad-e-jarb may be attributed to the Jali (detergent), Qatil-e-kirm (antthelmintic), Dafa-e-ta' affun (disinfectant), Musakkin (soothing), Qabiz (astringent), and Muhallil (resolvent) properties of the different ingredient present in it. On its local application, mites are killed due to Qatil-e-kirm (antthelmintic) and Dafa-e-ta' affun (disinfectant) actions of Kameela, Gandhak and Tutiya Sabz, while Jali (detergent) and Muhallil (resolvent) properties of Murdar Sang help remove the morbid matter from the affected area. Also the Muhallil (resolvent) and Mundamil-e-Qurooh (cicatrizant) properties of Kameela and Murdar Sang help in healing of lesions, and due to Musakkin and Mubarrid actions of Murad Sang, itching is reduced.<sup>13,18,28,30,31,32</sup>

## CONCLUSION

The study inferred that both the test and standard drugs are safe; test drug may be comparatively proclaimed as safe and effective in treatment of Jarb (Scabies). No adverse effect was observed during and after the study in either group. The limitation of the study was small sample size. Hence, larger sample size with controlled study designs may be conducted to further prove the efficacy of trail formulation.

## ACKNOWLEDGEMENT

Authors are thankful to the Director, National Institute of Unani Medicine, Bengaluru, Karnataka for providing facilities during the clinical trial.

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**Cite this article as:**

Ziaul Haque, Tanzeel Ahmad, Mohd Khalid, Danish Mand. Therapeutic evaluation of Zimad-e-jarb in jarb (Scabies): A single blind randomized controlled study. *J Biol Sci Opin* 2016;4(5):171-175 <http://dx.doi.org/10.7897/2321-6328.04540>

Source of support: Nil; Conflict of interest: None Declared

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