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A randomized controlled clinical study to evaluate efficacy and safety of a topical Unani formulation in the management of *Nār Fārsī* (Eczema)

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Nar Farsi (Eczema) is a very common skin inflammatory disorder. Its prevalence varies according to age groups and country to country. The Unani system of medicine offers its successful management. In this study, efficacy and safety of a topical Unani formulation was assessed and compared with a standard drug. A prospective, non inferiority, randomized, active controlled and parallel group study was designed to study 60 participants of eczema (30 participants in each group). The Unani formulation Marham Safeda Kafoori was studied as a test drug for 6 weeks versus allopathic medicine Clobetasol Propionate in the study. The study findings suggested that the Unani formulation was non inferior to Clobetasol Propionate in terms of percentage of reduction in itching, oozing, exudation, erythema, lichenification and cracking at 6 weeks of treatment. It was observed that the difference of the mean±SD of SASSAD Score was measured as 12.83±4.76 and 14.13±5.27 in test and control groups respectively. The result was analysed as per protocol and it was found that the efficacy of the Unani formulation was statistically significant ($p<0.001$). This study concluded that the Unani formulation was safe and effective in the treatment of eczema.

Keywords: Dermatitis, Itching, Marham Safeda Kafoori, Nar Farsi, Unani formulation

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Eczema is a very common skin disorder in all age groups. It is characterized by a changeable intensity of itching and soreness and in variable degrees a range of signs including dryness, erythema, excoriation, exudation, fissuring, hyperkeratosis, lichenification, papulation, scaling and vesiculation[1]. The prevalence of this disease lies between 2% and 3% of all dermatology consultation[2]. Contact dermatitis accounts for 4% to 7% of all patients presenting to the dermatology clinics[3]. Hand and foot eczema is the commonest type of contact dermatitis. The teenagers suffer from this disease in proportion to 15.2% and in the case of adults the prevalence is higher and can reach 18.6%. There is a lifetime risk of developing hand eczema of 20%[4]. In the Unani system of medicine, the pathogenesis of this disease is humoral in nature. Any derangement in quality and quantity of any of the four humours bilious (safra), melancholic (sauda), phlegmatic (balgham) and sanguine (dam) may lead to the development of this disease[5-9],

Contact dermatitis can be divided into two types: irritant contact dermatitis and allergic contact dermatitis. The presentations are similar in each type. Irritant contact dermatitis is the result of direct damage to the skin by an allergen[4]. So its onset can be rapid, within minutes of being exposed. Whereas allergic contact dermatitis is due to a delayed hypersensitivity reaction, which present generally after 48 h of exposure to allergens[10].

Eczema is a disability disease. It produces socio-economic problems for the patients. The patients having any forms of eczema may have sleeplessness, anxiety, personality disorder and inability to perform daily routine work. In conclusion, this ailment disrupts the quality of life of the patients[11-13]. The diagnosis of this disease is simple. However, detection of allergens and their avoidance are very difficult. In conventional medicine therapeutics for topical as well as systemic use are available. But they have limitations. Non-response to the therapy, recurrence of the disease, side effects of the drugs and complete avoidance of allergens are the prominent limitations, which leads to a quest for a newer and better drug. These circumstances have attracted renewed interest in the Unani system of medicine. Unani system of medicine offers treatment for skin

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disorders and adopts a holistic approach to provide complete cure to any health problem. The Unani pharmacopoeia contains many formulations for the treatment of eczema. They have been documented after a long time of clinical practice. In this study, we selected the formulation *Marham Safeda Kafoori,* an animo-herbo-mineral formulation from the Unani pharmacopoeia Qarabadeen Azam wa Akmal[14,15]. This formulation has been indicated for eczema, but it has never been studied in any clinical study to document its efficacy and safety so that its effectiveness can be established to be used as a potent drug for eczema in clinical practice.

Materials and Methods

This study was conducted with 60 participants of eczema at Central Research Institute of Unani Medicine (CRIUM), Hyderabad during June 2018 and July 2019. The participants were recruited from the outdoor patient department of CRIUM hospital. This study was registered in the Clinical Trial Registry-India (CTRI) under registration No. CTRI/2017/12/010957 dated 17/10/2017 after Institutional Ethics Committee approval of the protocol, written informed consent form and case record form of the study (EC Ref. No.38-18/2015-16/CRIUM/Hyd/IEC/05/M, dated 07.08.2017).

Sample size estimation

The total sample size of this study was 75 participants including expected 25% dropout. The sample size of 60 participants in this academic study was taken empirically. This study was designed as non-inferiority, randomized, single-blind (assessor blinded), parallel group and active-controlled. Participants of any sex in the age group of 18 to 65 years having any 3 clinical features itching, erythema, excoriation, scaling, hyperpigmentation, burning sensation and lichenification were included in the study. The participants having concomitant therapy, those who had comorbid diseases or those suffering from diabetes mellitus, hypertension, hepatic disorders and pregnant and lactating women were not included in the study.

Enrollment of participants

The first participant was enrolled in the study after its registration in the Clinical Trial Registry-India. The participants fulfilling the inclusion and exclusion criteria were given a Participant Information Sheet (PIS) to go through its contents and get clarified if there was any query and signed the informed consent form to participate in the study. The participants were randomized into test group (n=30) and control group (n=30) at a ratio of 1:1 as per the pre-specified scheme of block randomization generated by a computer (block of 4 participants). The sequence of the block was concealed in sequentially numbered, opaque, sealed envelopes. In total, 112 participants were screened. But 25 participants did not fulfill the inclusion and exclusion criteria and 5 participants did not provide consent to participate in the study. 82 participants was enrolled into the study. 60 participants could complete the duration of protocol therapy of 6 weeks. The Figure 1 shows the flow of the participants in the clinical trial.

Intervention

We selected Marham Safeda Kafoori (MSK), a Unani pharmacopeial formulation, constituted of animo-herbo-mineral single drugs for its safety and efficacy study**.** The ingredients of the formulation MSK has been displayed in Table 1. All the ingredients were identified by the experts in the Pharmacy Section and Survey of Medicinal Plant Unit

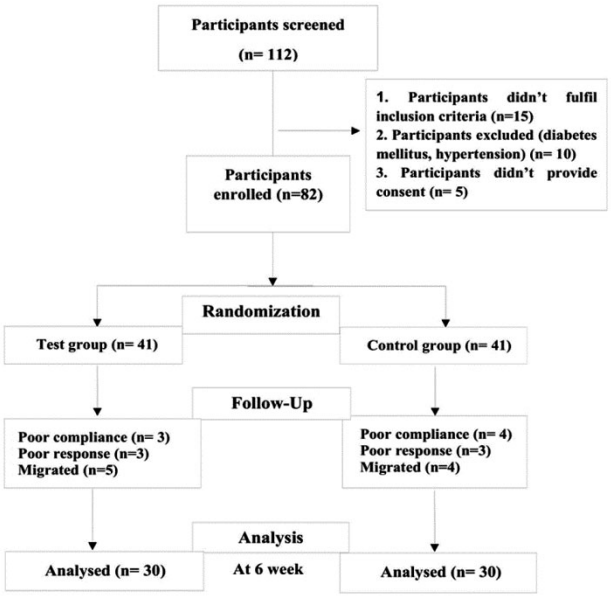

Fig. 1 — CONSORT flow diagram of the participants in the clinical trial

Table 1 — The composition of MSK

S. N.	Ingredients	Weight
1	Mom Safaid (*Pure wax)*	4.50 g
2	Raughan-e-Gul (*Rosa damascena,* Mill)	22.5 g
3	Safedab (*Zinc oxide*)	4.50 g
4	Murdar Sang (*Lead oxide*)	4.50 g
5	Safedi Baiza (*Egg albumin*)	40.0 g
6	Kafoor *(Cinnamomum camphora* (L.) *J. Presl*)	2.00 g

(SMPU) of the institute. The Unani formulation was prepared in a single batch as per standard operating procedure mentioned in Unani pharmacopoeia[14]. Clobetasol propionate was used as a controlled drug in the dosage form of ointment for local application[16].

Assessment of efficacy and safety

The primary endpoint of the study was either completion of 6 weeks of treatment or cure of the disease before 6 weeks of treatment. The efficacy of the formulation was assessed clinically. The severity of eczema was assessed by SASSAD (Six Area Six Signs of Atopic Dermatitis) Score (score: 0=Absent, 1=Mild, 2=Moderate, 3=Severe)[17]. The improvement in subjective parameters itching, dryness, erythema, oozing/exudation, scaling, excoriation and lichenification was recorded in a SASSAD score at baseline, every follow ups and at 6 weeks of the treatment. The photographs of every lesion of the participants were taken at baseline and post treatment. Local and systemic safety was assessed during the course of the therapy. Haematological and biochemical parameters were observed at baseline and after 6-week treatment.

Statistical analysis

In the present study, the descriptive and inferential statistical analysis had been carried out. The results of continuous and categorical data were presented in mean±SD and frequency (percentage) respectively. Student t-test (two-tailed, dependent) was used to find the statistical significance of study parameters. $p<0.05$ was considered for statistical significance. The statistical software SPSS 15.0 had been used for the analysis of data. The graphs and tables had been generated using Microsoft Excel 2016. Good Clinical Practice (GCP) guidelines had been followed for data collection.

Observations and Results

This study was designed as non-inferior, randomized and active-controlled. We conducted this study to assess the efficacy and safety of the Unani pharmacopeial formulation MSK in the management of eczema. The clinical and demographic profiles of the participants are given in Table 2. The baseline characteristics of the participants were almost similar in both groups. The mean age of the participants was 39.6 years and 44.06 years in the test and control groups respectively. There were 11 males and 19 females in each group. The average chronicity of the illness was 2.6 months and 2.8 months in the test and control groups respectively. We observed majority of the participants in the age group 31-40 years i.e., 15 participants. In addition, the temperament of the participants was balghami in 34 (56.7%), damvi in 16 (26.7%), safravi in 6 (10%) and saudavi in 4 (6.7%) participants. 17 (28.3%) participants in the test group and 12 (20%) participants in the control group belonged to the lower middle class of socio-economic status.

This study showed that the participants in the test group had itching (83.3%), papules (60%), erythema (76.7%), dryness (83%), exudation (73.3%), cracking (43.3%), localize swelling (60%) and lichenification (63.3%) whereas the participants in the control group had itching (76.7%), papules (60%), erythema (93.3%), dryness (90%), exudation (76.7%), cracking (56.7%), localized swelling (70%) and lichenification (46.7%). In this study the Unani formulation showed improvement (test group vs. control group) in itching (60% vs. 76.7%), papules (100% vs. 86.7%), erythema (86.7% vs. 86.7%), dryness (100% vs. 100%), exudation (96% vs. 90%), cracking (76.6% vs. 86.7%), localize swelling (73.4% vs. 93.4%) and lichenification (73.3% vs. 73.4%). The Tables 3-6 display the improvement in itching,

Table 2 — Demographic profiles of the participants

S. N.	Variables	Test group	Control group
1	No of participants,	30	30
2	Average age (years)	39.6	44.06
3	Male, n (%)	11 (36.7)	11(36.7)
4	Female, n (%)	19 (66.3)	19 (66.3)
5	Average chronicity	2.6 months	2.8 months
6	Positive family history, n	3	2
7	Co-morbidity, n	2	4

Table 3 — Effect of the formulations on Itching

Itching	Test group (n=30)			Control group (n=30)		
	Baseline	Post Treatment	% Changes	Baseline	Post Treatment	% Changes
Absent	0 (0%)	18 (60%)	60.0%	0 (0%)	23 (76.7%)	76.7%
Mild	0 (0%)	12 (40%)	40.0%	0 (0%)	7 (23.3%)	23.3%
Moderate	5 (16.7%)	0 (0%)	-16.7%	7 (23.3%)	0 (0%)	-23.3%
Severe	25 (83.3%)	0 (0%)	-83.3%	23 (76.7%)	0 (0%)	-76.7%
Total	30 (100%)	30 (100%)	-	30 (100%)	30 (100%)	-

Table 4 — Effect of the formulations on erythema

Erythema	Test group (n=30)			Control group (n=30)		
	Baseline	Post Treatment	% Changes	Baseline	Post Treatment	% Changes
Absent	0 (0%)	26 (86.7%)	86.7%	0 (0%)	26 (86.7%)	86.7%
Mild	0 (0%)	4 (13.3%)	13.3%	0 (0%)	4 (13.3%)	13.3%
Moderate	7 (23.3%)	0 (0%)	-23.3%	2 (6.7%)	0 (0%)	-6.7%
Severe	23 (76.7%)	0 (0%)	-76.7%	28 (93.3%)	0 (0%)	-93.3
Total	30 (100%)	30 (100%)	-	30 (100%)	30 (100%)	-

Table 5 — Effect of the formulations on exudation

Exudation	Test group (n=30)			Control group (n=30)		
	Baseline	Post Treatment	% Changes	Baseline	Post Treatment	% Changes
Absent	0 (0%)	29 (96.7%)	96.7%	2 (6.7%)	29 (96.7%)	90%
Mild	6 (20%)	1 (3.3%)	-16.4%	5 (16.7%)	1 (3.3%)	3.3%
Moderate	22 (73.3%)	0 (0%)	-73.3	23 (76.7%)	0 (0%)	-76%
Severe	2 (6.7%)	0 (0%)	-6.7	0 (0%)	0 (0%)	-
Total	30 (100%)	30 (100%)	-	30 (100%)	30 (100%)	-

Table 6 — Effect of the formulations on lichenification

Lichenification	Test group (n=30)			Control group (n=30)		
	Baseline	Post Treatment	% Changes	Baseline	Post Treatment	% Changes
Absent	8 (26.7%)	30 (100%)	73.3%	4 (13.3%)	26 (86.7%)	73.4%
Mild	14 (46.7%)	0 (0%)	-46.7%	19 (63.3%)	4 (13.3%)	-50.0%
Moderate	8 (26.7%)	0 (0%)	-26.7%	7 (23.3%)	0 (0%)	-23.30
Severe	0 (0%)	0 (0%)	-	0 (0%)	0 (0%)	-
Total	30 (100%)	30 (100%)	-	30 (100%)	30 (100%)	-

Table 7 — Effect of the formulations on SASSAD Score

	Test group (n=30)				Control group (n=30)			
	Min-Max	Mean±SD	Mean difference±SD	p-value	Min-Max	Mean±SD	Mean difference±SD	p-value
Baseline	9-26	14.50±5.36	-	-	9-28	13.43±4.35	-	-
F1	8-24	13.50±4.9	1.00±0.95	<.001	8-24	12.47±4.01	0.967±0.1	<001
F2	5-2	11.17±4.38	3.33±1.75	<001	6-22	10.27±3.9	3.167±1.42	<001
F3	4-16	8.20±2.91	6.30±2.88	<001	4-16	7.57±2.83	5.867±1.96	<001
F4	3-12	5.77±2.45	8.73±3.05	<001	2-12	5.20±1.96	8.233±2.61	<001
F5	0-8	3.67±2.45	10.83±3.95	<001	0-6	3.13±1.68	10.300±3.56	<001
Post Treatment	0-2	0.37±0.7	14.13±5.27	<001	0-11	0.60±2.08	12.833±4.76	<001

erythema, exudation, and lichenification after 6 weeks of treatment with test formulation and control drug.

Assessment of the efficacy of the Unani formulation was made on the basis of reduction in cumulative score assigned for the signs and symptoms based on SASSAD SCALE (Six Area Six Signs of Atopic Dermatitis) at 6 weeks of treatment compared to baseline. The mean (±SD) SASSAD Score in the participants of the test group (n=30) at baseline was 13.43±4.35 whereas 14.50±5.36 in the control group. It was observed that after 6 weeks of treatment the mean (±SD) SASSAD Score was reduced to 0.60±2.02 and 0.37±0.66 in the test and control groups respectively. The difference of the mean (±SD) SASSAD Score was measured 12.83±4.76 and 14.13±5.27 in the test and control groups respectively. The mean (±SD) SASSAD Score at baseline and post treatment in the test and control groups has been displayed in Table 7. The result was analysed as per protocol criteria and it was found that the reduction in mean (±SD) SASSAD Score post treatment was statistically significant ($p<0.001$) when compared to baseline in the test and control groups. When the reduction in mean (±SD) SASSAD score was compared inter group, the difference was not statistically significant. However, the Unani formulation was found clinically effective in reducing the symptoms and signs of eczema. The efficacy of the Unani formulation was comparable to the

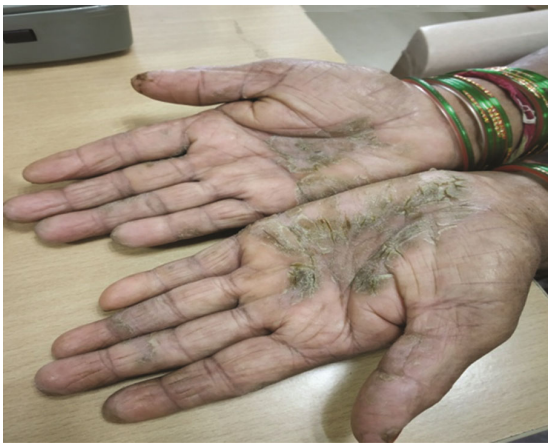

Fig. 2 — Before treatment

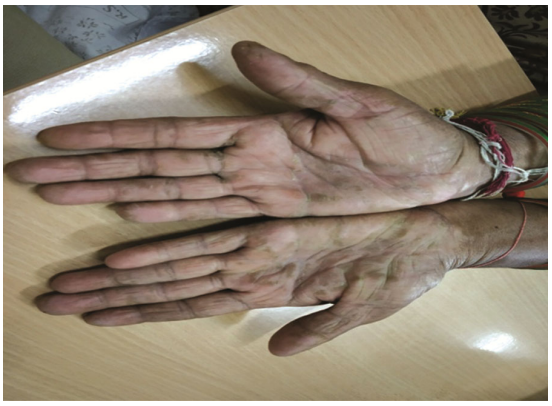

Fig. 3 — After treatment

controlled drug clobetasol propionate. In our study the Unani formulation may be considered as non-inferior to control drug in the management of eczema. The Figures 2 and 3 show the response of the Unani formulation on eczema.

In this study, the local and systemic safety of the test and control drugs was assessed. It was observed that the Unani formulation was tolerated well and found safe. The test drug showed no local and systemic adverse effect and toxicity during the course of the therapy. Poor response of the Unani formulation was observed after 6 weeks of treatment in three participants only. In addition, the control drug clobetasol propionate was also tolerated well by all the participants in the control group. The control drug demonstrated no local and systemic adverse effect till the end of 6 weeks therapy. In this group, three participants did not show response to the control drug, too. When compared to baseline, the haematological and biochemical parameters did not change after 6 weeks of treatment in both the groups.

Discussion

This study revealed that the Unani formulation was effective in reducing symptoms and signs of eczema. Our study demonstrated that the Unani formulation MSK alleviated the symptoms itching, exudation and cracking and the signs papules, erythema, lichenification, dryness and localized swelling at 6 weeks of treatment compared to baseline. The efficacy exhibited by MSK might be possible due to medicinal properties of the individual constituents of MSK. Mom Safaid (Pure Wax), a good murakhkhi (emollient) and jali (detergent) drug may be responsible for the improvement in itching and dryness of the lesion[18-19]. The drugs Kafoor (*Cinnamomum camphora*), Roughan-e-gul (Oil of *Rosa damascena*), Safedab (*Zinc oxide*) and Safedi Baiza (*Egg albumin*) are known to have musakkin (anodyne) property might also be responsible in reducing itching[21–24]. It was observed that MSK resolved papules and erythema in a significant number of the participants. This effect of the formulation may be attributed to the muhallil (resolvent) property of Mom *Safaid*, Raughan-e-gul and Murdarsang[20,22,25]. The drugs Raughan e gul, Murdarsang and Safedab are mudammil-e- qurooh (cicatrizant/healing agent) which may have acted synergistically to heal papules and erythema[22,26]. The Unani formulation showed improvement in exudation in the study. This effect of the formulation may be attributed to the jali (detergent) action of Mom safaid, dafi'-i-ta'affun (antiseptic) property of Murdarsang and Kafoor and mujaffif-i- ratoobat (desiccant) action of Safedab[20-23,27]. It was also observed that Unani formulation was effective in the alleviation of skin cracking. The possible reason for this effect of the Unani formulation might be due to murakhkhi (emollient) action of Mom safaid, Raughan-e-gul, munbit-e-laham (muscle grower) properties of Murdarsang and Safedab[18,19,22,23]. The drugs with emollient potential had been found effective in reducing symptoms of eczema in several clinical studies[12,17]. The Unani formulation also reduced localized swelling on the eczematous lesion. Mohallil (resolvent) action of Mom safaid, Raughan-e-gul, Murdarsang and Kafoor might be responsible for this effect of the Unani formulation[20,22,27]. This study also showed that the Unani formulation was effective in the improvement of lichenification which might be attributed to the mulattif (demulcent), murakhkhi (emollient) and mohallil (resolvent) actions of Mom

safaid and mohallil (resolvent) action of Raughan-e-gul and Murdarsang[20,22,23].

Clinical efficacy of some Unani formulations in eczema had been reported in a few studies. Nawab *et al*[2] reported that topical application of a non-pharmacopoeial formulation alleviated itching, erythema and papules in eczematous lesions after 42 days of treatment. The control drug clobetasol propionate demonstrated efficacy in the reduction of itching, exudation, erythema and lichenification in the control group. The similar observation was reported in another clinical study conducted by Mayur Claria *et al* that clobetasol propionate was found to be responsive to the manifestations of chronic eczema and showed significant improvement in reduction in the degree of inflammation and itching[28].

There were several limitations in this study. The study was conducted on a small sample size (n=30 each group), the duration of protocol therapy was very short and the time period for completion of the study was two years. The study was meant for academic purpose. So, there was the limitation of the funds, too.

Conclusion

This clinical study assessed and compared the efficacy and safety of topical Unani formulation Marham Safeda Kafoori (MSK) against Clobetasol Propionate. The findings of the study suggested that the Unani formulation was not inferior to Clobetasol propionate in terms of percentage of reduction in itching, dryness, erythema, oozing/exudation, scaling, excoriation and lichenification. This study was the first attempt to conduct a clinical trial of Unani formulation versus allopathic medicine Clobetasol propionate, which had already been found effective in the management of eczema. The outcome demonstrated in the study that the Unani formulation could be a promising drug for eczema. The leads in the study could be utilized to design another study with a large sample size to establish the efficacy of MSK in the management of eczema. Although this formulation has been used as a therapeutic for eczema for a long time, the efficacy and safety of the formulation have been in question before the scientific community due to lack of any clinical study demonstrating the efficacy of MSK. This study revealed that the Unani formulation MSK was safe and effective. There was no adverse effect reported during the study. It is, therefore, concluded that the Unani formulation MSK may be used as a safe and effective drug for treating eczema.

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Conflict of interest

Authors have no conflict of interest in publication of this original paper.

Authors' contributions

KA conducted the study and drafted the manuscript, MN supervised the study, analyzed the data and edited the manuscript and MHK vetted and approved the manuscript.

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