

# Comparative Effect of *Prosopis cineraria* Ointment and Eucerin Softener on Eczema Area and Severity Index (EASI) score changes in Patients with Atopic Dermatitis

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## Abstract

**Background:** Atopic Dermatitis is a chronic skin disease resulting in itching, redness, scratching, and thickening of skin. This study aimed to compare effects of *Prosopis cineraria* ointment and Eucerin on EASI score changes in patients with atopic dermatitis in Yazd. **Methods:** This study was a double-blind randomized controlled clinical trial carried out on 44 patients with mild to moderate atopic dermatitis. Patients were divided into two (intervention and control) groups of *Prosopis cineraria* ointment and Eucerin. Participants, researchers, and evaluators of the results were unaware of the cans containing the drug until the study was completed. The study duration was four weeks and patients were studied at baseline and at the end of the first, second and fourth weeks. After history and careful examination, EASI criterion was used to evaluate the severity of atopic dermatitis. Data was analyzed through SPSS 16 using independent t-test, and repeated measure ANOVA.  $P < 0.05$  was considered significant. **Results:** The mean age of the patients in the intervention and control groups was 22.72 and 21.77 years old, respectively. Examination of the relationship between treatment group and gender showed that there was a significant statistical relationship difference ( $p = 0.003$ ). Regarding thickness, redness, excoriation and lichenification at any of the four time intervals, there was no difference between the intervention and control groups. Regarding itching, none of the four time intervals showed significant difference in two groups, but the second time there was significant difference ( $p = 0.044$ ). In addition, no drug side effects were reported in any of the treatment groups. **Conclusion:** The effect that *Prosopis cineraria* has on improving the symptoms of atopic dermatitis can be as high as the Eucerin but the mean EASI score was smaller in the *Prosopis cineraria* group in all four times of symptom assessment.

**Keywords:** *Prosopis cineraria*, Eucerin, Eczema, EASI, Atopic dermatitis

## INTRODUCTION

Eczema is a type of skin inflammation that includes itching, redness, dryness of the skin and elevated serum IgE levels, when atopic dermatitis is one of the most common types of Eczema <sup>[1]</sup>. Atopic Dermatitis is a chronic skin disease that often begins during infancy and usually in the first year of birth and can cause sleep disturbances, anxiety, and disorders in educational and social status <sup>[2]</sup>.

The disease manifests itself with erythematous lesions and is usually seen in the flexor areas of the limbs and wrists in 2-5 year old children and disappears in up to 16% in 60% of cases <sup>[3]</sup>. The prevalence of atopic dermatitis in children in developed countries is 15% to 20% <sup>[4]</sup>. The prevalence of the disease has increased in recent decades, with no specific reason for this increase <sup>[5]</sup>. In a study conducted in Germany,

increasing age and birth weight have been found effective in increasing the incidence of atopic dermatitis <sup>[6]</sup>. In a study in the United Kingdom, however, preterm birth has been

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identified as a risk factor for dermatitis [7]. Researchers in the United States have found that increasing age at birth is effective in developing the disease, while no association has been reported between birth weight gain and the occurrence of atopic dermatitis [8].

The main treatment for this disease is the use of corticosteroids and topical softeners, while complications of corticosteroids such as skin atrophy, decreased collagen synthesis and pigmentation of the skin, cataract, glaucoma and osteoporosis have restricted their use [9]. Moisturizers play a useful role in the treatment of dry skin, while steroids are good for treating inflamed and red skin [10]. The efficacy of topical and safe topical corticosteroids has been proven for a short time, but in the medium to long term, it is not easy to decide on their use in atopic dermatitis [11].

The rich flora of Iranian herbs as well as the rich knowledge of using herbs makes it necessary to pay attention to the use of herbs for the treatment of diseases. One of the medicinal herbs is *Prosopis cineraria*, which grows in the southern coasts of Iran and in the provinces of Sistan and Baluchestan, Hormozgan, Bushehr, Khuzestan and southern Fars. Among the medicinal properties of *Prosopis cineraria* are its antimicrobial, anti-diabetic, anti-spasmodic, soothing and anti-inflammatory properties [12].

*Prosopis cineraria* is a flowering tree found in southern region of Iran and extends along the Persian Gulf shore, and Oman sea. *Prosopis cineraria* is also known as the "Wonderful tree" and also as the "king of desert". Some medicinal properties of *Prosopis cineraria* are its antimicrobial, anti-diabetic, anti-spasmodic, soothing and anti-inflammatory properties [13]. *Prosopis cineraria* in Iran is called "Kahour" showing therapeutic effects on various diseases such as bronchitis, asthma, worms, diarrhea and leukoderma. *Prosopis cineraria* flowers accompanied by sugar is used during pregnancy to prevent miscarriage. The leaves of *Prosopis cineraria* are prescribed to treat eye diseases. Additionally, wood ash of *Prosopis cineraria* is rubbed on the skin to remove hair [14].

However, the effect of this plant on the improvement of atopic dermatitis has not been investigated in clinical trials. The aim of this study was to compare the effect of *Prosopis cineraria* ointment with Eucerin softener as a routine treatment on clinical symptoms in patients with atopic dermatitis.

## METHODS AND MATERIALS

This study was a double-blind randomized controlled clinical trial that was performed on 44 patients with mild to moderate atopic dermatitis. The patients were selected based on physical examination, family history and personal history by Hanifin and Rajka criteria. After explaining the purpose of the study and obtaining written informed consent, they were divided into two groups of *Prosopis cineraria* ointment and

Eucerin softener. The participants, researchers, and evaluators of the results were unaware of the cans containing the drug until the study was completed.

The study duration was four weeks and the patients were studied at baseline and at the end of the first, second and fourth weeks. Demographic data include age, sex and disease that are recorded in a questionnaire. After history and careful examination, EASI (Eczema Area and Severity Index) criterion was used to evaluate the severity of atopic dermatitis i.e. clinical symptoms such as redness (erythema, inflammation), thickness (induration, papulation, and edema), excoriation (scratching) and lichenification (lined skin, prurigo nodules-chronic eczema) according to the questionnaire form. During the course of treatment, participants were not allowed to use systemic treatments, including corticosteroids and other topical medications. If some serious event happened, the participants would be excluded by the researcher. Participants were also not allowed to withdraw from the study at any time. Sample size was calculated based on the mean of symptom severity changes according to EASI [15]. The extract of *Prosopis cineraria* is extracted according to the following method. We chopped a certain amount (10 gr) of the stem of the plant and then soaked it in 100 ml of ethanol solvent and 30% water for 12 hours at 70 °C in the Ultra Sonic bath [16]. We passed the solution through filter paper, concentrated the filtered solution at 50 °C, and then sterilized the resulting extract to be added to the Eucerin softener in a certain ratio (3 to 100) to obtain an ointment containing the extract of the *Prosopis cineraria* plant, which will be used for treatment.

## Ethical considerations

This study was approved by the Ethics Committee of the Shahid Sadoughi University of Medical Sciences in I. R. Iran, protocol number IR.SSU. REC.1397.154. All procedures performed in studies involving human participants in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments. All participants were informed and provided written consent.

## Statistical analysis

Data was analyzed by SPSS software. To evaluate the effect of intervention on EASI changes, independent T-test, and repeated measure ANOVA were used. P value of less than 0.05 was considered as significant level in all tests.

## RESULTS

The mean age of the patients in the intervention group was 22.72 years old and in the control group was 21.77 years old. The intervention group consisted of 6 men and 16 women. The control group included 16 men and 6 women. Examination of the relationship between treatment group and gender showed that there was a significant statistical relationship difference ( $p=0.003$ ). Furthermore, age distribution showed that there was a statistically significant

difference between the two groups regarding mean age. There was no significant difference ( $p=0.865$ ).

Regarding thickness at any of the four time intervals, there was no difference between the intervention and control groups (Table 1). Regarding excoriation, there was no significant difference between the intervention and control groups (Table 2). The results showed that there was no significant difference between the intervention and control groups regarding redness in any of the four intervals (Table 3). Regarding lichenification, there was no difference between the intervention and control groups in the four time intervals (Table 4). Regarding itching, none of the four time intervals showed significant difference between the intervention and control groups, but for the second time there was significant difference (Table 5). In addition, no drug side effects were reported in any of the treatment groups. The mean EASI score of study participants by treatment groups at different times was presented in table 6 and figure 1.

## DISCUSSION

There are various therapies for Atopic dermatitis while avoidance of stimuli is the base of any treatment. Topical treatments include moisturizers, topical corticosteroids, and calcineurin inhibitors. Systemic therapies include antibiotics, antihistamines, antidepressants, systemic corticosteroids, and immune-system-mediating drugs such as cyclosporine and phototherapy.

The main treatment for this disease is the use of topical softeners and corticosteroids, but complications of corticosteroids such as skin atrophy, decreased collagen synthesis, decreased pigmentation of the skin, percutaneous dermatitis, cataract, osteoporosis, and glucose intolerance have limited their use [17].

Moisturizers play a useful role in treating dry skin, while steroids are good for treating inflamed and red skin. The efficacy of topical and safe topical corticosteroids has been proven for a short time, but in the medium to long term, it is not easy to decide on their use in atopic dermatitis [11]. Plants have been used as medicines for the past few decades and today, despite advances in the science and development of synthetic drugs, medicinal herbs are still widely used and traditional medicine is being restored [18].

The aim of this study was to compare the effect of *Prosopis cineraria* ointment and Eucerin on clinical symptoms in patients with atopic dermatitis. The results of this study showed that EASI score was not significantly different in the two groups. The mean score at the time of referral was 21.05 in the intervention group and 23.25 in the control group ( $p=0.449$ ) and the mean of the end of the fourth week was 20.27 in the intervention group and 24.7 in the control group. It was not statistically significant ( $p=0.247$ ). No study was found on the effect of *Prosopis cineraria* on atopic dermatitis. Therefore, it is not possible to compare the results of this

study with similar studies, and therefore a number of trials in the field of treatment of atopic dermatitis are mentioned:

In a study aimed to investigate the antimicrobial effects of the hydroalcoholic extract of *Prosopis cineraria*, Taheri et al, concluded that the extract showed antimicrobial activity after autoclaving. This study showed that concentrations of 40 and 80 mg/ml had the greatest effect on *Staphylococcus aureus*, which was significantly different from other treatments and standard antibiotics. On the other hand, *Prosopis cineraria* extract had no effect on *Pseudomonas aeruginosa*. The concentration of 80 mg/ml had the highest effect on *Escherichia coli* and *Vibrio cholerae*. There was a significant difference between all other treatments [19].

In the present study, *Prosopis cineraria* were considered as the main intervention with no difference in EASI score with the routine treatment group (Eucerin). However, the effect of Eucerin on the treatment of atopic dermatitis has been proven. For example, in a study of 64 children between the ages of 3 months and 12 years old who were treated with Eucerin for 14 days, symptoms of dermatitis improved [20]. Since the mean EASI score in both treatment groups decreased during the treatment period and there was no significant difference between the treatment time and symptom scores at all four time points of assessment and follow-up, it can be concluded that atopic dermatitis symptoms improved. It can occur in children using both *Prosopis cineraria* and Eucerin.

## CONCLUSION

The effect that *Prosopis cineraria* has on improving the symptoms of atopic dermatitis can be as high as the usual treatment (Eucerin). It should be noted that in the present study, there was no significant difference between the mean EASI score in the two treatment groups, but the mean EASI score was smaller in the treated group (*prosopis cineraria*) at all four times of symptom assessment.

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**Table 1:** The thickness score in *Prosopis cineraria* Ointment and Eucerin Softener groups

Time	Group	Mean rank	P value
Before intervention	Intervention	22.86	0.831
	Control	22.14	
First week	Intervention	22.16	0.831
	Control	22.84	
Second week	Intervention	21.50	0.509
	Control	23.50	
Fourth week	Intervention	23.02	0.752
	Control	21.98	

**Table 2:** The excoriation score in *Prosopis cineraria* Ointment and Eucerin Softener groups

Time	Group	Mean rank	P value
Before intervention	Intervention	22.32	0.638
	Control	21.68	
First week	Intervention	21.50	0.563
	Control	23.50	
Second week	Intervention	23.84	0.419
	Control	21.16	
Fourth week	Intervention	21.32	0.452
	Control	23.68	

**Table 3:** The redness score in *Prosopis cineraria* Ointment and Eucerin Softener groups

Time	Group	Mean rank	P value
Before intervention	Intervention	22.80	0.860
	Control	22.20	
First week	Intervention	22.23	0.871
	Control	22.77	
Second week	Intervention	23.20	0.680
	Control	21.80	
Fourth week	Intervention	22.34	0.919
	Control	22.66	

**Table 4:** The lichenification score in *Prosopis cineraria* Ointment and Eucerin Softener groups

Time	Group	Mean rank	P value
Before intervention	Intervention	22.64	0.940
	Control	22.36	
First week	Intervention	20.14	0.193
	Control	24.86	
Second week	Intervention	22.02	0.757

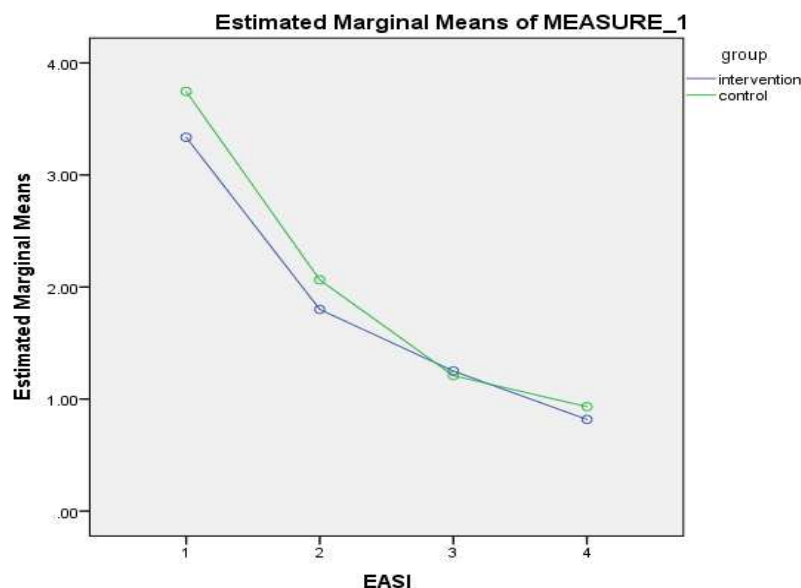
Fourth week	Control	22.98	0.503
	Intervention	21.50	
	Control	23.50	

**Table 5:** The itching score in *Prosopis cineraria* Ointment and Eucerin Softener groups

Time	Group	Mean rank	P value
Before intervention	Intervention	21.89	0.747
	Control	23.11	
First week	Intervention	20.70	0.341
	Control	24.30	
Second week	Intervention	18.84	0.044
	Control	26.16	
Fourth week	Intervention	19.25	0.070
	Control	25.75	

**Table 6:** The mean EASI score of study participants by treatment groups at different times

Time	Intervention group		Control group		P value
	Mean	SD	Mean	SD	
EASI score before intervention	3.34	3.41	3.74	2.58	0.449
EASI score at first week	1.80	2.33	2.06	1.50	0.238
EASI score at second week	1.25	1.81	1.21	0.87	0.262
EASI score at fourth week	0.82	1.04	0.93	0.76	0.247



**Figure 1:** The mean EASI score of study participants by treatment groups at different times