

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison of the Effect of Prosopis Ointment with Eucerin Emollient on Clinical Signs of Patients with Atopic Dermatitis

#### Protocol summary

##### Study aim

Determination and comparison of Prosopis extract ointment with Eucerin emollient on clinical outcomes in patients with atopic dermatitis

##### Design

Randomized, double-blind with parallel control group clinical trial

##### Settings and conduct

Patients with atopic dermatitis referring to Shahid Bagheypour skin clinic are given cream Prosopis (A) or Eucerin emollient (B). The patients are not aware of the type of drug they are assigned to. The groups were also coded A and B to the statistical analyzer.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study include: patients with typical atopic dermatitis are mild to moderate and exclusion criteria include: patients with psoriasis; any allergy to the ointment provided; bacterial infection or synchronous systemic disease (except asthma and allergic rhinitis).

##### Intervention groups

Intervention group: use of topical product of Prosopis Ointment 3% 1FTU (finger tip unit) twice daily for a palm of the body for 6 weeks. Control group: use of topical Eucerin Softener 1FTU (finger tip unit) twice daily for 6 weeks.

##### Main outcome variables

Eczema area and severity index

#### General information

##### Reason for update

End of getting patients and end of project

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190220042770N1**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **prospective**

Last update: **2020-08-04, 1399/05/14**

Update count: **1**

##### Registration date

2019-03-09, 1397/12/18

##### Registrant information

###### Name

Sayed Kamal Hosseinian Nodushan

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3223 8915

###### Email address

sk.hosseinian@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-13, 1397/12/22

##### Expected recruitment end date

2019-06-05, 1398/03/15

##### Actual recruitment start date

2019-03-16, 1397/12/25

##### Actual recruitment end date

2019-09-24, 1398/07/02

##### Trial completion date

2019-11-04, 1398/08/13

##### Scientific title

Comparison of the Effect of Prosopis Ointment with Eucerin Emollient on Clinical Signs of Patients with Atopic Dermatitis

##### Public title

Effect of Prosopis Ointment in Dermatitis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patients with Typical lesions of Mild to Moderate Atopic Dermatitis

**Exclusion criteria:**

Patients with Psoriasis Sensitivity to Ointment Concurrent Bacterial infection or Systemic disease (except Asthma and Allergic Rhinitis)

**Age**

No age limit

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **44**

Actual sample size reached: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

This study was designed simple randomization method using random numbers table. The ointments are coded by the statistic consultant (a and b), the researcher, physicians, and patients do not know the contents of ointment.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients will be randomized (black design) in two groups treated with ointment prepared from the Herb extract and Emollient. Ointments are identical in appearance and aroma, coding and labeling are protected in a computer program.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

SEthics committee of Shahid Sadoughi University of Medical Sciences

**Street address**

Shahid Sadoughi Blvd., Central Office of the University of Medical Sciences

**City**

Yazd

**Province**

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**Postal code**

8951737915

**Approval date**

2019-01-22, 1397/11/02

**Ethics committee reference number**

IR.SSU.REC.1397.154

**Health conditions studied**

**1**

**Description of health condition studied**

Atopic Dermatitis

**ICD-10 code**

L20.9

**ICD-10 code description**

Atopic dermatitis, unspecified

**Primary outcomes**

**1**

**Description**

Eczema area and Severity index

**Timepoint**

Before starting treatment and ending weeks 1 and 3 and 6

**Method of measurement**

EASI Questionnaire for Atopic Dermatitis

**Secondary outcomes**

**1**

**Description**

Erythema

**Timepoint**

Before starting treatment and week 1, 3 and 6

**Method of measurement**

EASI Questionnaire for Atopic Dermatitis

**2**

**Description**

Tickness

**Timepoint**

Before starting treatment and week 1, 3 and 6

**Method of measurement**

EASI Questionnaire for Atopic Dermatitis

**3**

**Description**

Scratching or Excoriation

**Timepoint**

Before starting treatment and week 1, 3 and 6

**Method of measurement**

EASI Questionnaire for Atopic Dermatitis

**4**

**Description**

Lichenification

**Timepoint**

Before starting treatment and week 1, 3 and 6

**Method of measurement**

EASI Questionnaire for Atopic Dermatitis

**Intervention groups****1****Description**

Intervention group: Prosopis ointment twice a day for 14 days

**Category**

Treatment - Drugs

**2****Description**

Control group: Eucerin twice a day for 14 days

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Sadoughi Hospital, Shahid Baghei Pour Clinic

**Full name of responsible person**

Seyed Kamal Hosseinian Nodushan

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Central office of Shahid Sadoughi University of  
Medical Sciences, Shahid Bahonar Square

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Masoud Mirzae

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Yazd University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Sayed Kamal Hosseinian Nodushan

**Position**

PhD student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Traditional Medicine

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Associate professor

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Ph.D.

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Sayed Kamal Hosseinian nodushan

**Position**

PhD student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Street address**