

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 Hosseini Nodushan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3223 8915

Email address

sk.hosseini@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

Yazd

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
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Sponsors / Funding sources

- 1**
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Full name of responsible person
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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
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Position
PhD student
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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