Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 pationts 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

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

Seyed Kamal Hosseinian Nodushan

Street address

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

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3724 0171

Email

sk.hosseinian@mail.ssu.ac.ir

Web page address

http://ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzae

Street address

Shahid Sadoughi Blvd

City

Yazd

Province

Yazd

Postal code

8951737915

Phone

+98 35 3726 3154

Email

info@ssu.ac.ir

Web page address

http://web.ssu.ac.ir/

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

Street address

No 1, Etehadie Alley, Shahid Sadoughi Blvd

City

Yazd

Province

Yazd

Postal code

8951737915

Phone

+98 35 3733 0122

Email

sk.hosseinian@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Majid Emtiazy

Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Shahid Sadoughi Blvd
City
Yazd
Province
Yazd
Postal code
8951737915
Phone
+98 35 3223 8915
Email
dr.emtiazy@yahoo.com
Web page address
http://ssu.ac.ir/

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
Traditional Medicine
Street address
Shahid Sadoughi Blvd
City
Yazd
Province
Yazd
Postal code
8951737915
Phone
+98 35 3821 7545
Email
shkamalreza@gmail.com

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