Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison the effectiveness of Malva Sylvesteris ointment with Oserin demulcent in treatment of atopic dermatitis in 6 months to 12 years old groups

Protocol summary

Study aim
Properties of patented topical formula containing extract of Malva Sylvesteris according to pharmacognostic formulated standards will be compared with Oserin demulcent in improvement of signs of erythema, edema, excoriation and lichenification in mild to moderate atopic dermatitis

Design
A double blind randomized clinical trial will be performed

Settings and conduct
This clinical trial will be performed with two 22 persons groups after explanation the procedure for patients and filling out consent forms by them and then intervention group will use a finger tip of patented herbal topical formulation of Malva Sylvesteris for one hand of affected body surface twice daily and in return investigation group use Oserin ointment in the same way

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with mild to moderate atopic dermatitis lesions in aged between six months to 12 years old Exclusion criteria: Psoriasis; patients with allergic reactions to Malva Sylvesteris; history of oral corticosteroid or antihistamine consumption in the last week or topical steroid in the last 3 weeks

Intervention groups
22 persons who take Malva Sylvesteris ointments

Main outcome variables
Improvement of sings and symptoms of mild to moderate atopic dermatitis lesions

General information

Reason for update

Acronym
Not

IRCT registration information
IRCT registration number: **IRCT20170107031814N2**
Registration date: **2018-05-11, 1397/02/21**
Registration timing: **prospective**

Last update: **2018-05-11, 1397/02/21**
Update count: **0**

Registration date
2018-05-11, 1397/02/21

Registrant information

Name
Mahshid Meyssami

Name of organization / entity
Shahid Sadoughei Univercity Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice Chancellor for Research,Shahid Sadoughei University of Medical Saciences

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2018-08-23, 1397/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison the effectiveness of Malva Sylvesteris

ointment with Oserin demulcent in treatment of atopic dermatitis in 6 months to 12 years old groups

Public title
Effect of Malva Sylvesteris oitment in treatment of atopic eczema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with mild to moderate atopic dermatitis lesions All patient with mild to moderate atopic dermatitis lesions aged between 6 months to 12 years old
Exclusion criteria:
Psoriasis Patients with Allergic Reactions to Malva Sylvesteris History of corticosteroid or antihistamine consumption in the last week or use of topical steroid in the last three weeks in all patients
Age
From **6 months** old to **12 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
By dividing patients in two groups A and B Group A received Malva Sylvesteris ointment in a tube without label and group B received placebo in a similar color as group A
Placebo
Used
Assignment
Parallel
Other design features
Not

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Yazd University of Medical Sciences
Street address
Centeral Departement of Shahid Sadoughi Medical University, Shahid Bahonar square
City
Yazd
Province
Yazd
Postal code
8916978477
Approval date
2016-12-26, 1395/10/06
Ethics committee reference number
IR.SSU.REC.1395.196

Health conditions studied

1

Description of health condition studied
Atopic dermatitis
ICD-10 code
L20-L20.0-
ICD-10 code description
Atopic dermatitis; Besnier prurigo; other atopic dermatitis; atopic dermatitis unspecified

Primary outcomes

1

Description
Time for improvement of signs of atopic dermatitis lesions
Timepoint
In first physical examination then after one week then every other week until six weeks
Method of measurement
By taking pictures and filling out the forms

Secondary outcomes

1

Description
Allergy to applied treatment or Infection
Timepoint
During treatment
Method of measurement
Visit by expert physician

Intervention groups

1

Description
Intervention group: Use of a fingertip of patented herbal topical formulation of MalvaSylvesteris extract for one hand of affected body surface with atopic dermatitis lesions twice daily and following the improvement of signs of dermatitis lesions after one week and then every

other week until six weeks

Category

Treatment - Drugs

2

Description

Control group: Use of a fingertip of Oserin ointment for one hand of affected body surface with atopic dermatitis lesions twice daily and following the improvement of signs of dermatitis lesions after one week and then every other week until six weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Yazd, Yazd Health Network, Khatamolanbia Clinic

Full name of responsible person

Mahshid Meyssami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Mahshid Meyssami

Position

PHD candidate

Latest degree

Medical doctor

Other areas of specialty/work

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Latest degree

Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

For privacy of informations

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available