

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison the effectiveness of Malva Sylvestris 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 Sylvestris 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 Sylvestris 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 Sylvestris; 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 Sylvestris 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

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shahid Sadoughei University of Medical Scienes

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 Sylvestris

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

Public title
Effect of Malva Sylvesteris ointment 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

Central Departement of Shahid Sadoughi Medical University, Shahid Bahonar square

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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, Khatamolania Clinic

Full name of responsible person

Mahshid Meyssami

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

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

Full name of responsible person

Mahshid Meyssami

Position

PHD candidate

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Dr. Majid Emtiazy

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

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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