Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the efficacy of topical cream based on Iranian traditional medicine containing Tragacanth, White wax and Bitter almond oil on the symptoms management of Eczema (clinical study) and it’s comparison with Mometasone 0.1%

Protocol summary

Study aim

Evaluating the efficacy of topical cream based on Iranian traditional medicine containing Tragacanth, White wax and Bitter almond oil on the symptoms management of Eczema (clinical study) and it’s comparison with Mometasone 0.1%

Design

The study design is an intervention, randomized to intervention and control groups, double-blind and phase 3 clinical trials.

Settings and conduct

The clinical part of this study is performed in the general clinic of Razi dermatology hospital in Tehran. The blinding of the study is done in a way that the containers are labeled by the researcher, and patients are initially told that when you participate in the project, you are randomly given a herbal or chemical cream, so the patient is And the doctor is not aware of the consumed content. The data is also shown to Code Specialist A through Code B to blind him to the research.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: - Men and women 18 years or older - One or more eczema lesions in the palm or back area - Mild to moderate plaques - Patients who have not received topical, oral, or injectable medications for the treatment of eczema in the past week (emulsion use was permitted). Lack of infection or malignancy at the site of treatment (no problem with closed wounds). - Patient's consent to participate in the study Exclusion criteria include: - Under 18 years Pregnancy and lactation Whole body eczema - Patients with other skin lesions - Taking other topical medicines while participating in research Patients taking systemic immunosuppressive drugs or biological drugs. Infection or skin malignancy at the treatment site

Intervention groups

Herbal cream (intervention group) or mometasone cream (control group)

Main outcome variables

There will be no consequences for the participants.

General information

Reason for update

Edit information after completing the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20190914044767N1**
Registration date: **2019-12-19, 1398/09/28**
Registration timing: **prospective**

Last update: **2024-09-20, 1403/06/30**
Update count: **1**

Registration date

2019-12-19, 1398/09/28

Registrant information

Name

zahra ghadimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2264 0051

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zahraghadimi1393@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-21, 1398/09/30

Expected recruitment end date
2020-01-04, 1398/10/14
Actual recruitment start date
2019-12-23, 1398/10/02
Actual recruitment end date
2020-02-03, 1398/11/14
Trial completion date
2020-02-26, 1398/12/07

Scientific title
Evaluating the efficacy of topical cream based on Iranian traditional medicine containing Tragacanth, White wax and Bitter almond oil on the symptoms management of Eczema (clinical study) and it’s comparison with Mometasone 0.1%

Public title
Effect of topical cream ,containing Tragacanth on the Eczema and it’s comparison with Mometasone 0.1%
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Men and women 18 years or older One or more eczema lesions in the palm or back area Mild to moderate plaques Patients who have not received topical, oral, or injectable medication for the treatment of eczema in the last week (emulsion use is permitted). Lack of infection or malignancy at the treatment site (no problem with closed wounds). Patient's consent to participate in the study
Exclusion criteria:
Under 18 years Pregnancy and lactation Eczema generalize Patients with other skin lesions Taking other topical medicines while participating in the research Patients taking immunosuppressive systemic drugs or biological drugs. Infection or skin malignancy at the treatment site
Age
From **18 years** old to **99 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **42**
Actual sample size reached: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was performed in a randomized, individualized, block with statistical software. The randomization list is available to the researcher. and given to the participants, according to the order of the herbal cream (intervention group) or the mometasone cream (control group). The herbal cream containers are labeled blue and the mometasone cream containers are labeled red; shown in the randomization list in letters A and B, respectively.
Blinding (investigator's opinion)
Double blinded
Blinding description
The blinding of the study is done in a way that the labels of the medicine containers are labeled by the researcher, and patients are initially told that when you participate in the project, you are randomly given a herbal or chemical cream, so Patient and physician are not aware of consumed content. The data is also shown to the data analyzer by code A and B.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Faculty of Pharmacy and Pharmaceutical Sciences, Islamic Azad University of Medi
Street address
Faculty of Pharmacy and Pharmaceutical Sciences Islamic Azad University of Medical Sciences, First Yakhchal Street, Gholak, Dr. Shariati Street
City
Tehran
Province
Tehran
Postal code
1941933111
Approval date
2018-12-30, 1397/10/09
Ethics committee reference number
IR.IAU.PS.REC.1397.354

2

Ethics committee
Name of ethics committee
Ethics Committee Deputy of Research and Technology Shahid Beheshti University of Medical Sciences
Street address
Next to Ayatollah Taleghani Hospital, Shahid Arababi Street, Yemen Strest, Shahid Chamran Highway,
City
Tehran
Province
Tehran
Postal code
1983963113

Approval date
2019-09-01, 1398/06/10
Ethics committee reference number
IR.SBMU.RETECH.REC.1398.192

Health conditions studied

1

Description of health condition studied
Mild to moderate hand eczema
ICD-10 code
L20
ICD-10 code description
Atopic dermatitis

Primary outcomes

1

Description
Atopic dermatitis disease intensity
Timepoint
At the beginning of the study and about 20 days after starting the topical cream (after treatment)
Method of measurement
SCORAD Index form

2

Description
Duration of recovery
Timepoint
About 20 days after starting the topical cream (after treatment)
Method of measurement
Patient Tracking and Evaluation with SCORAD and DLQI

Secondary outcomes

1

Description
Quality of dermatology patient's life
Timepoint
At the beginning of the study and about 20 days after starting the topical cream (after treatment)
Method of measurement
DLQI questionnaire

Intervention groups

1

Description
Control group: The group receiving the cream is Momtazone 0.1% manufactured by Kish Medifarm Company in Iran. The cream is applied for 3 weeks every night and then for 2 weeks every other night until they heal.
Category
Treatment - Drugs

2

Description
Intervention group: The group receiving the cream consists of a tragacanth made by a researcher at the Shahid Beheshti Traditional School of Medicine Laboratory in Iran, applied the cream every night until healing.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Robabe Abedini
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Vahdat Eslami Square, Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Traditional Medicine & Materia Medica Research center Shahid Beheshti university of Medical Sciences
Full name of responsible person
Somayeh Esmaili
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No 19, Tavanir Street, Hemmat Highway
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Email

itmrc@sbmu.ac.ir
Web page address
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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
Traditional Medicine & Materia Medica Research center Shahid Beheshti 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
Islamic Azad University
Full name of responsible person
Zahra Ghadimi
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
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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