

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 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)

Phone

+98 21 2264 0051

Email address

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

Street address

Vahdat Eslami Square, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0174

Fax

+98 21 5562 0300

Email

razihospital@sina.tums.ac.ir

Web page address

<http://razihos.tums.ac.ir>

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

Street address

No 19, Tavanir Street, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

198396313

Phone

+98 21 8877 6027

Fax

+98 21 8877 6027

Email

itmrc@sbmu.ac.ir

Web page address

<http://tmrc.sbmu.ac.ir>

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

Medical Pharmacy

Street address

First Yakhchal Street., Golhak , Dr. Shariati Ave.

City

Tehran

Province

Tehran

Postal code

1941933111

Phone

+98 21 2264 0051

Fax

+98 21 2260 2059

Email

Zahraghadimi1393@gmail.com

Web page address

<http://iaups.iautmu.ac.ir/fa>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Robabe Abedini

Position

Associate Professor, Faculty specialist physician

Latest degree

Specialist

Other areas of specialty/work

Dermatology

Street address

Vahdat Eslami Square, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5563 0174

Fax

+98 21 5562 0300

Email

r.abed@yahoo.com

Web page address

<http://razihos.tums.ac.ir>

Person responsible for updating data

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

Medical Pharmacy

Street address

First Yakhchal Street., Golhak , Dr. Shariati Ave.

City

Tehran

Province

Tehran

Postal code

1941933111

Phone

+98 21 2264 0051

Fax

+98 21 2260 2059

Email

Zahraghadimi1393@gmail.com

Web page address

<http://iaups.iautmu.ac.ir/fa>

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