

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Cream Containing Date Extract in the Treatment of Patients with Eczema

#### Protocol summary

##### Study aim

The aim of this study is to treat eczema using a cream formulation containing date extract.

##### Design

The clinical trial has a control group and a patient group and over 50 patients.

##### Settings and conduct

The study site is the Dermatology and Leprosy Research Center of Tehran University of Medical Sciences. All patients use a cream containing date extract for 4 weeks. The cream is used daily in patients / twice a day, each time they should use the cream on the entire surface of skin lesions.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria for patients with mild to moderate eczema. Conditions not included in the study, patients with underlying diseases.

##### Intervention groups

The intervention groups are patients and the control groups. Patient groups will use a cream formulation containing date extract daily / twice a day. Control groups will also receive standard treatments for eczema.

##### Main outcome variables

Itching rate; skin inflammation

#### General information

##### Reason for update

More time is needed to check the stability of the formulation. Also, clinical studies require more time for eczema patients to refer to the skin center.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211127053186N1**

Registration date: **2022-05-23, 1401/03/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-30, 1402/10/09**

Update count: **1**

##### Registration date

2022-05-23, 1401/03/02

##### Registrant information

###### Name

Somayeh Handali

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6412 1510

###### Email address

s-handali@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-20, 1400/12/01

##### Expected recruitment end date

2025-03-18, 1403/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Cream Containing Date Extract in the Treatment of Patients with Eczema

##### Public title

"Evaluation of the Effect of Date Cream in the Treatment of Eczema"

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Patients with mild to moderate eczema may be eligible

for admission

**Exclusion criteria:**

People who have underlying diseases. People who very old and difficult to get information from them.

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 50

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

NO

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

thics committee of Tehran Medical University of Medical Sciences

**Street address**

Tehran University of Medical Sciences, Poursina Avenue, Qods Street, Enqelab Square, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۱۷۶۱۴۴۱۱

**Approval date**

2021-11-06, 1400/08/15

**Ethics committee reference number**

IR.TUMS.TIPS.REC.1400.147

**Health conditions studied**

1

**Description of health condition studied**

Eczema disease

**ICD-10 code**

L20.84

**ICD-10 code description**

Intrinsic (allergic) eczema

**Primary outcomes**

1

**Description**

"itching rate"

**Timepoint**

Periods include assessing the amount of pruritus before and after treatment for two weeks.

**Method of measurement**

standard skin questionnaire

2

**Description**

the rate of inflammation

**Timepoint**

Periods include assessing the extent of inflammation before and after treatment for two weeks.

**Method of measurement**

a questionnaire

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

This cream will be prepared by Tarbiat Modares University. Intervention group (patients with mild or moderate eczema): Cream containing date extract will be used to control and treat eczema. All patients use a cream containing date extract for 4 weeks. Use the cream daily / twice a day, each time you should use the cream on the entire surface of skin lesions. The cream contains date extract, Stearic acid, Spermaceti, Glycerin, Benzyl alcohol and Cetyl alcohol.

**Category**

Treatment - Drugs

2

**Description**

Control group: standard treatments will be used. The standard treatment for eczema is topical corticosteroids such as Triamcinolone twice daily

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Dermatology and Leprosy Research Center of Tehran

University of Medical Sciences  
**Full name of responsible person**  
Soamyeh Handali  
**Street address**  
Tehran University of Medical Sciences, Poursina  
Avenue, Qods Street, Enqelab Square, Tehran, Iran.  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tehran 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

Tehran 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**

Tehran University of Medical Sciences  
**Full name of responsible person**  
Soamyeh Handali  
**Position**  
University faculty  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Phone**

+98 21 6412 1510

**Email**

s-handali@sina.tums.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Publication of results after the end of the study

**When the data will become available and for how long**

After the end of the study

**To whom data/document is available**

All people

**Under which criteria data/document could be used**

These data will be available to all groups to know the effectiveness of the cream formulation containing date extract in the treatment of eczema.

**From where data/document is obtainable**

School of Pharmacy and Dermatology and Leprosy Research Center, Tehran University of Medical Sciences  
Somayeh Handali 09161147998 handali\_s81@yahoo.com

**What processes are involved for a request to access data/document**

Search in the internet for accessing results

**Comments**

NO