

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Clinical trials for comparison between the efficacy of the fig fruit extract cream, hydrocortisone ointment and placebo on the severity of skin lesions in children up to 15 years of age with mild to moderate atopic dermatitis

#### Protocol summary

##### Summary

This study is a double-blind, randomized clinical trial (RCTs) to compare the efficacy of extract the fig fruit cream with topical corticosteroid ointment and placebo in children with atopic dermatitis. Forty five children up to 15 years of age with mild to moderate atopic dermatitis who refer to the dermatology clinic at Shohada Hospital and the asthma and allergy clinic at Mofid Hospital will participate in the study. The severity of clinical symptoms of atopic dermatitis must be less than 50 based on the scoring atopic dermatitis index. Patients with severe atopic dermatitis, systemic disease, or immune deficiency disorders are excluded. Moreover, Users of systemic drugs during last 4 weeks or topical drugs during last 2 weeks for atopic dermatitis treatment will be excluded from the study. Eligible patients will be randomized into following groups: fig fruit extract (n=15), hydrocortisone (n=15) and Farabi base cream as a placebo (n=15) by using block randomization method. Each cream is used twice a day for two weeks. After two weeks, the overall severity of symptoms will be evaluated by the scoring atopic dermatitis index. All patients will be re-examined after one month.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014101419529N1**  
Registration date: **2015-03-11, 1393/12/20**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-03-11, 1393/12/20

##### Registrant information

###### Name

Shirin Abbasi

###### Name of organization / entity

Faculty of Traditional Medicine

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3855 2189

###### Email address

abbasish931@mums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research of Mashhad University of Medical Sciences

##### Expected recruitment start date

2015-02-20, 1393/12/01

##### Expected recruitment end date

2015-06-22, 1394/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Clinical trials for comparison between the efficacy of the fig fruit extract cream, hydrocortisone ointment and placebo on the severity of skin lesions in children up to 15 years of age with mild to moderate atopic dermatitis

##### Public title

Fig fruit extract cream and hydrocortisone ointment in

atopic dermatitis

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: Children up to 15 years of age with mild to moderate atopic dermatitis exclusion criteria: 1- Children with severe atopic dermatitis. 2- Children with systemic disease, other skin disease, immune deficiency or skin infections. 3- Users of systemic drugs during last 4 weeks or topical drugs during last 2 weeks for atopic dermatitis treatment. 4- Patients who do not desired to stay in the study.

### **Age**

From **1 day** old to **15 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **45**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

The Fig cream, Hydrocortisone ointment and Farabi base cream were packed in identical tubes which differed only with respect to coding and both patients and clinicians were blinded to the treatment group to maintain the double blind nature of the study.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee, Mashhad University of Medical Sciences

##### **Street address**

Ghoreishi Building, Daneshgah Street

##### **City**

Mashhad

##### **Postal code**

#### **Approval date**

2014-12-06, 1393/09/15

#### **Ethics committee reference number**

research/930235/1/281

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Atopic Dermatitis

#### **ICD-10 code**

L20

#### **ICD-10 code description**

Atopic Dermatitis

## **Primary outcomes**

### 1

#### **Description**

Clinical severity of cutaneous lesions

#### **Timepoint**

At baseline, at the end of the treatment course(2 weeks later), one month after the cessation of the treatment

#### **Method of measurement**

SCORAD index

## **Secondary outcomes**

### 1

#### **Description**

Recurrence of cutaneous lesions

#### **Timepoint**

1 month after the cessation of the treatment

#### **Method of measurement**

Physical exam and history taking

## **Intervention groups**

### 1

#### **Description**

Patients in intervention group should use the fig fruit extract cream twice daily for 2 weeks on all cutaneous lesions of the whole body.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Patients in control group should use hydrocortisone ointment twice daily for 2 weeks on all cutaneous lesions of the whole body.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Patients in placebo group should use Farabi base cream twice daily for 2 weeks on all cutaneous lesions of the whole body.

#### **Category**

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Shohada Tajrish Hospital

**Full name of responsible person**

DR. Mehdi Qaisari

**Street address**

Qhods Sq. Shahr-dari St. Shohada Tajrish Hospital

**City**

Tehran

### 2

#### Recruitment center

**Name of recruitment center**

Mofid Children Hosp

**Full name of responsible person**

DR. Mehdi Qaisari

**Street address**

Mofid Children Hosp. next to the Hoseinie-Ershad,  
Shariati Ave.

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research of Mashhad University of  
Medical Sciences

**Full name of responsible person**

Said Islame

**Street address**

Ghoreish Building, Daneshgah Street, Mashhad

**City**

Mashhad

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Mashhad University of  
Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**

Faculty of Traditional Medicine

**Full name of responsible person**

Shirin Abbasi

**Position**

Physician, PhD student

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

#### Contact

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assistant professor

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## Person responsible for updating data

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**Web page address**

## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*