

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The evaluation of efficacy of marshmallow ointment (1%) in comparison with topical hydrocortisone (1%) on children with atopic dermatitis

#### Protocol summary

##### Summary

**Objectives:** The objective of this study is evaluation of efficacy of marshmallow ointment in comparison with topical hydrocortisone on children with atopic dermatitis. **Design:** This is a double-blinded clinical trial study with a 22 sample size that done new cases of mild to mod atopic dermatitis with ages ranging from 3 months to 12 years old age in two therapeutic groups (marshmallow and hydrocortisone) by using permuted blocks. **Setting and conduct:** Patients apply medications three a day and follow in a 4-week period. **Participants including major eligibility criteria:** Inclusion criteria: 1) The age of patients range from 3 months to 12 year 2) The patient has no history of contact dermatitis to prescription drugs 3) Patients with acute infection is localized 4) According to the SCORAD severity of the disease is between 50-25. **Exclusion criteria:** changes in the level and score of SCORAD. **Intervention:** One group of patients receive marshmallow cream (1%) and the other one hydrocortisone ointment (1%). Patients in both groups receive the drug three times a day. **Main outcome measures:** Disease severity measure based on the criteria SCOARD in the first day, the seventh day, the thirtieth day

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2017020831205N2**

Registration date: **2017-04-03, 1396/01/14**

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

Last update:

Update count: **0**

##### Registration date

2017-04-03, 1396/01/14

#### Registrant information

##### Name

Mohsen Naseri

##### Name of organization / entity

Traditional Iranian Medicine Clinical Trial Research

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2288 2596

##### Email address

r.jafari.hajati@gmail.com

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research of Shahid Beheshti University of Medical Sciences and Health Services, Tehran

#### Expected recruitment start date

2016-11-21, 1395/09/01

#### Expected recruitment end date

2017-05-22, 1396/03/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The evaluation of efficacy of marshmallow ointment (1%) in comparison with topical hydrocortisone (1%) on children with atopic dermatitis

#### Public title

The effect of marshmallow and hydrocortisone ointment in children with atopic dermatitis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: The age of patients ranged from 3

months to 12 year; The patient has no history of contact dermatitis to prescription drugs; Patients with acute infection is localized; According to the SCORAD severity of the disease is between 50-25. Exclusion criteria: changes in the level and score of SCORAD

#### Age

From **3 months** old to **12 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **22**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

This study is completely randomized block design.

## Secondary Ids

### 1

#### Registry name

not used

#### Secondary trial Id

not used

#### Registration date

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences and Health Services, Tehran

##### Street address

next Ayatollah Taleghani Hospital, Shahid Arabi street, Yemen street, Chamran highway

##### City

Tehran

##### Postal code

#### Approval date

2013-03-10, 1391/12/20

#### Ethics committee reference number

91/132

## 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

Disease severity based on the criteria SCORAD

#### Timepoint

the first day intervention, the seventh day intervention, the thirtieth day intervention

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

not used

#### Timepoint

not used

#### Method of measurement

not used

## Intervention groups

### 1

#### Description

Intervention group 1: Receive marshmallow ointment (1%) three times a day. This ointment produced by the School of Pharmacy, Shahid Beheshti University of Medical Sciences and Health Services in Tehran

#### Category

Treatment - Drugs

### 2

#### Description

control group: not used

#### Category

N/A

### 3

#### Description

Intervention group 2: Receive hydrocortisone ointment (1%) three times a day. This ointment produced by the School of Pharmacy, Shahid Beheshti University of Medical Sciences and Health Services in Tehran

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Immunology and Allergy Clinic of Mofid Hospital

**Full name of responsible person**

Dr. Vahede Naseri

**Street address**

Before Mirdamad, Above Hoseynieh Ershad, Shari'ai street

**City**

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice Chancellor for research of Shahid Beheshti University of Medical Sciences and Health Services,

**Full name of responsible person**

Afshin Zarghi

**Street address**

next Ayatollah Taleghani Hospital, Shahid Arabi street, Yemen street, Chamran highway

**City**

Tehran

**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 Shahid Beheshti University of Medical Sciences and Health Services,

**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**

Traditional Iranian Medicine Clinical Trial

**Full name of responsible person**

Mohsen Naseri

**Position**

Boss of Traditional Iranian Medicine Clinical Trial

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

second floor, 1471 Plaque, Shahed University research centers, Kargar Shomali, Enghelab square

**City**

Tehran

**Postal code****Phone**

+98 21 6646 4320

**Fax****Email**

naserishahed@yahoo.com, r.jafari.hajati@gmail.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Traditional Iranian Medicine Clinical Trial Research

**Full name of responsible person**

Mohsen Naseri

**Position**

Boos of Traditional Iranian Medicine Clinical Trial Research

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

Second floor, 1471 Plaque, Shahed University research centers, Kargar Shomali, Enghelab square

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**Fax****Email**

naserishahed@yahoo.com, r.jafari.hajati@gmail.com

**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**

Traditional Iranian Medicine Clinical Trial Research

**Full name of responsible person**

Razieh Jafari Hajati

**Position**

Expert of Traditional Iranian Medicine Clinical Trial Research

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

Second floor, 1471 Plaque, Shahed University research centers, Kargar Shomali, Enghelab square

**City**

Tehran

**Postal code****Phone**

+98 66464320

**Fax****Email****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*