

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

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Email address

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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**

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Full name of responsible person

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Position

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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