

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of plantago ointment on improving the symptoms of patients with atopic dermatitis

Protocol summary

Study aim

Determining the effect of Barhang ointment on atopic dermatitis in patients referred to the dermatology clinics of Javad Al-A'meh Clinic in 1401

Design

Clinical trial with control group with parallel groups, double-blind, randomized by quadruple block method, phase 3 on 48 patients

Settings and conduct

Patients with atopic dermatitis referred to dermatology clinics in Kerman are diagnosed based on scorad criteria and are included in the study based on the criteria for entering and obtaining informed consent. Patients are divided into two groups based on randomization of quadruple block and those receiving deciduous ointment and those receiving placebo, so that the number of patients with atopic dermatitis is the same in both groups. The intervention is performed for 2 months before and after the course. scorad are compared for response to treatment The two-way blind method is used to blind the participant, researcher, clinical caregiver, outcome assessor and data analyst.

Participants/Inclusion and exclusion criteria

Patients with atopic dermatitis Admission according to scorad criteria, mild to moderate dermatitis, poor response to routine treatment, absence of infection, written consent Failure to enter in case of receiving oral or injectable steroids, symptoms of intolerance, presence of disease that reduces drug absorption, lack of regular participation

Intervention groups

Barhang ointment receiving group Placebo group

Main outcome variables

Erythema, dryness, edema, discharge, thickening, itchy skin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200304046695N1**

Registration date: **2022-07-01, 1401/04/10**

Registration timing: **prospective**

Last update: **2022-07-01, 1401/04/10**

Update count: **0**

Registration date

2022-07-01, 1401/04/10

Registrant information

Name

Zohreh Zandvakil

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3222 9776

Email address

zandvakilz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2023-01-21, 1401/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of plantago ointment on improving the symptoms of patients with atopic dermatitis

Public title

The effect of plantago ointment on atopic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Approval of Hanifin and Rajka criteria for atopic dermatitis Mild to moderate atopic dermatitis (SCORAD <50) Poor response to conventional therapies (topical steroids and antihistamines) Absence of exudate or infection Concomitant presence of systemic disease or dermatitis except atopic dermatitis Written and informed consent of the patient

Exclusion criteria:

Taking oral or injectable steroids, antibiotics, phototherapy, and other immunosuppressive treatments (such as cyclosporine and azathioprine) but the corticosteroid position is not contraindicated. Day Symptoms of drug intolerance such as severe heartburn and bloating Existence of diseases that interfere with drug absorption, such as inflammatory bowel disease Inability to participate regularly in follow-up

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a double-blind clinical trial that is conducted on patients with eczema in patients referred to Javad Al-A'meh Clinic in Kerman in 1401. Patients are randomly divided into two groups of drugs and placebo. Randomization is designed using the method of block size four by a statistician with the Allocation Random software as (BAAB), (ABBA), (AABB), (BBAB), (ABAB).... 48 envelopes (24 envelopes containing paper A for drug group) and (24 envelopes containing paper B for placebo group) are prepared and given to a trained person outside the research team (nurse) who is responsible for randomly assigning patients based on the method of block size four. The random allocation will be done consecutively until the sampling is completed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients with atopic dermatitis referred to dermatology clinics in Kerman are diagnosed based on scorad criteria and are included in the study based on the criteria for entering and obtaining informed consent. Patients are

divided into two groups receiving barhang ointment and receiving medication based on the randomization method of quadruple block, so that the number of patients with atopic dermatitis is the same in both groups. And this is done by someone other than the researcher, who does not know what group the person belongs to. The drug and the placebo are made by the pharmacist and are similar in shape, color and smell and are coded and the patient and the researcher do not know the type of drug.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2020-02-17, 1398/11/28

Ethics committee reference number

IR.Kmu.REC.1398.639

Health conditions studied**1****Description of health condition studied**

Dermatit Atopic

ICD-10 code

L20

ICD-10 code description

Atopic dermatitis

Primary outcomes**1****Description**

Skin erythema

Timepoint

Before the intervention, 2 months after taking the drug, 15 days after the end of the course

Method of measurement

Based on scorad criteria

2

Description

skin dryness

Timepoint

Before the intervention, 2 months after taking the drug,
15 days after the end of the course

Method of measurement

Based on scorad criteria

3

Description

Skin edema

Timepoint

Before the intervention, 2 months after taking the drug,
15 days after the end of the course

Method of measurement

Based on scorad criteria

4

Description

skin itching

Timepoint

Before the intervention, 2 months after taking the drug,
15 days after the end of the course

Method of measurement

Based on scorad criteria

5

Description

Skin discharge

Timepoint

Before the intervention, 2 months after taking the drug,
15 days after the end of the course

Method of measurement

Based on scorad criteria

6

Description

Thickening of the skin

Timepoint

Before the intervention, 2 months after taking the drug,
15 days after the end of the course

Method of measurement

Based on scorad criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:First, the flowering plant is collected

from Kerman Baft farms and after approval by a botanist, a herbarium sample is prepared. The collected plant is then dried in the shade. Then it is ground and passed through a mesh sieve 40. 100 g of the plant is boiled and filtered with 500 ml of water for 10 minutes and the extract is boiled until it is concentrated and dried in an oven at 50 ° C. To prepare the ointment, 5% of the leaf extract is added, 5 g of the extract dried by a thoroughly mortar mortar, 10 ml of glycerin and 85 g of osrine.

Category

Treatment - Drugs

2

Description

Control group:The placebo is prepared using 10 ml of glycerin and 85 g of oserin without adding turmeric extract. Oral brown dye is used to color the placebo with the main drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Javad Al-A'meh Specialized Medical Complex

Full name of responsible person

Zohreh Zandvakil

Street address

Kerman, Abuzarshamali St., Alley No. 25,
Javadalaimeh Medical Complex

City

Kerman

Province

Kerman

Postal code

7617763811

Phone

+98 34 3251 2098

Email

zandvakilz@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Dr. Reza Malekpour Afshar

Street address

Ebn-e-Sina St., Jahad Blvd., Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3226 3855

Email

Zandvakilz@gmail.com

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

Yes

Title of funding source

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Zohreh Zandvakil

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

Email

Zandvakilz@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Zohreh Zandvakil

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

Email

Zandvakilz@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Zohreh Zandvakil

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

Email

Zandvakilz@gmail.com

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