

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effects of *Fumaria parviflora*. L extract on chronic hand eczema: a randomized double-blind, placebo-controlled study

Protocol summary

Summary

Our objective is to evaluate the effect of alcoholic extract of FP on hand eczema. This randomized double-blind, placebo-controlled study assesses efficacy of alcoholic extract of FP on hand eczema. 44 patients are randomly assigned to apply 4% cream of FP or vehicle cream to hand twice daily for 4 weeks. The primary outcome is reduction of hand eczema and the evaluation is done by EASI score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138810303074N1**
Registration date: **2010-02-16, 1388/11/27**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-02-16, 1388/11/27

Registrant information

Name

Mehdi Pасalar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1233 7589

Email address

pasalar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2010-01-30, 1388/11/10

Expected recruitment end date

2010-03-01, 1388/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of *Fumaria parviflora*. L extract on chronic hand eczema: a randomized double-blind, placebo-controlled study

Public title

The effects of *Fumaria parviflora*. L extract on chronic hand eczema

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Healthy patients with hand eczema, not using topical medication in 2 weeks or systemic medication in one month prior to the study. Exclusion criteria: pregnancy or breast feeding, hypersensitivity to test medication

Age

From **12 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences Ethics Committee

Street address

Zand Bld.

City

Shiraz

Postal code

Approval date

1384-12-28, 765/01/-446

Ethics committee reference number

CT-84-2759

Health conditions studied

1

Description of health condition studied

Hand eczema

ICD-10 code

L20.8

ICD-10 code description

Diseases of the skin and subcutaneous tissue

Primary outcomes

1

Description

reduction of Hand eczema

Timepoint

before and and two weeks after termination of therapy

Method of measurement

eczema area and severity index (EASI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 4% topical cream of FP alcoholic extarct for 4 weeks, twice daily 10 grams on hand surface skin - control: vehicle cream as for treatment group

Category

Treatment - Drugs

2

Description

Control group: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Center for Traditional Med. and History of Med.

Full name of responsible person

Mehdi Pasalar

Street address

School of Medicine

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences, Vice Chancellor for Research

Full name of responsible person

Dr.Dabagh Manesh

Street address

Zand St.

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences, Vice Chancellor for Research

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

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Mehdi Pasalar

Position

MD. / MPH

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Farideh Jowkar

Position

MD, Assisstant Professor

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Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Farideh Jowkar

Position

Dermatologist

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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