Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Pasalar

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+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
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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