

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Clinical evaluation of efficacy of Viola odorata flowers in the treatment of atopic dermatitis in adults

Protocol summary

Summary

The aim of this study is to assess the efficacy of sweet violet flower in the treatment of atopic dermatitis in adults. The study is randomized, single-blind, without a placebo control and in 1-2 trial phase. The main objective of the study is treatment and from the type of intervention. The inclusion criteria include acute, subacute and chronic atopic eczema with mild to moderate severity and patients older than 12 years and the exclusion criteria are pregnancy, lactation, other types of dermatitis other than atopic dermatitis, psoriasis, atopic dermatitis with severe severity. The number of patients is 80 that 40 patients receive sweet violet flower and 40 patients take cetirizine. The intervention period is 14 days and the primary outcomes of the study include the type of eczema, eczema severity and score of the disease.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201606143922N3**

Registration date: **2016-06-20, 1395/03/31**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-06-20, 1395/03/31

Registrant information

Name

Masoud Modarresi

Name of organization / entity

Faculty of Pharmacy - Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1835 6168

Email address

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of efficacy of Viola odorata flowers in the treatment of atopic dermatitis in adults

Public title

Effect of sweet violet flower in the treatment of atopic dermatitis in adults

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: acute, subacute and chronic atopic eczema with mild to moderate severity; patients older than 12 years. Exclusion criteria: pregnancy; lactation; other types of dermatitis other than atopic dermatitis; psoriasis; atopic dermatitis with severe severity.

Age

From **12 years** old to **70 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Building
No. 2, Shaheed Beheshti Blv., Kermanshah

City

kermanshah

Postal code

Approval date

2016-05-11, 1395/02/22

Ethics committee reference number

KUMS.REC.1395.83

Health conditions studied

1

Description of health condition studied

Atopic dermatitis

ICD-10 code

L20.9

ICD-10 code description

Atopic dermatitis, unspecified

Primary outcomes

1

Description

type of eczema

Timepoint

the first day of the study

Method of measurement

questionnaire

2

Description

severity of eczema

Timepoint

the first day of the study, 14th day

Method of measurement

questionnaire

3

Description

score of the disease

Timepoint

the first day of the study, 14th day

Method of measurement

questionnaire

Secondary outcomes

1

Description

side effects

Timepoint

during the study

Method of measurement

questionnaire

Intervention groups

1

Description

In intervention group, extract of sweet violet flower
(capsule form) is given orally, 500 mg twice in a day for
14 consecutive days.

Category

Treatment - Drugs

2

Description

In control group, cetirizine is given orally, 10 mg once a
day for 14 consecutive days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Personal Office of Dermatologist

Full name of responsible person

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Behrooz Hamzeh

Street address

Kermanshah University of Medical Sciences, Building
No. 2, Shaheed Beheshti Blv., Kermanshah

City

Kermanshah

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

Yes

Title of funding source

Kermanshah University of Medical Sciences

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

Kermanshah University of Medical Sciences, Faculty
of Pharmacy

Full name of responsible person

Dr. Masoud modarresi

Position

Member of the scientific board of the university /
Associate Professor (Ph.D.)

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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