

# 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

mmodarresi@kums.ac.ir

###### 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.)

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

Faculty of Pharmacy, Parastar Blv., Daneshgah St.,  
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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Dr. Masoud Modarresi

**Position**

Member of the scientific board of the university /  
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## Person responsible for updating data

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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*