Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 recieve 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., Shaheed Shiroodi Blv.
City
Kermanshah
Postal code
Phone
+98 83 3427 6489
Fax
Email
mmodarresi@kums.ac.ir
Web page address

Person responsible for scientific 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., Shaheed Shiroodi Blv.
City
Kermanshah
Postal code
Phone
+98 83 3427 6489
Fax
Email
mmodarresi@kums.ac.ir
Web page address

Person responsible for updating data

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., Shaheed Shiroodi Blv.
City
Kermanshah
Postal code
Phone
+98 83 3427 6489
Fax
Email
mmodarresi@kums.ac.ir
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