Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Oral and Topical Curcumin versus Placebo in Improving Disease Severity, Itching, and Quality of Life in Patients with Mild to Severe Eczema

Protocol summary

Study aim
Determination of the Therapeutic Effects of Oral and Topical Curcumin in Patients with Eczema and Its Evaluation Compared to Placebo in Patients Attending Imam Reza Clinic, Shiraz, during 2024–2025

Design
The present study is a cross-sectional, single-blind, placebo-controlled clinical trial, which can be considered applied based on its objectives

Settings and conduct
72 patients with eczema attending the Asthma and Allergy Clinic of Imam Reza in 2024–2025 were assigned into three groups of 24 each: oral curcumin, topical curcumin, and control

Participants/Inclusion and exclusion criteria
Inclusion Criteria is:Patients aged 18 to 65 years Suffering from mild, moderate, or severe eczema based on the Eczema Area and Severity Index (EASI) Patients who have not previously received any treatment for eczema Exclusion Criteria is:Lack of consent to participate in the study,Significant organ dysfunction,Cutaneous malignancies,Generalized eczema,Pregnant or breastfeeding women,Women of childbearing age who do not use adequate contraception,Inability to adhere to treatment or attend regular follow-up visits

Intervention groups
1.Intervention Group 1: receiving oral curcumin
2.Intervention Group 2: receiving topical curcumin
3.Control Group: receiving placebo

Main outcome variables
Eczema severity/Pruritus severity/Skin-related quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250926067366N1**
Registration date: **2025-10-05, 1404/07/13**
Registration timing: **prospective**

Last update: **2025-10-05, 1404/07/13**
Update count: **0**

Registration date
2025-10-05, 1404/07/13

Registrant information

Name
Elham Amini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3628 0318

Email address
amini.elham9170@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Oral and Topical

Curcumin versus Placebo in Improving Disease Severity, Itching, and Quality of Life in Patients with Mild to Severe Eczema

Public title
Therapeutic Effects of Oral and Topical Curcumin in the Treatment of Eczema
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18 to 65 years Suffering from mild, moderate, or severe eczema based on Eczema Area and Severity Index Patients who have not previously received any treatment for eczema
Exclusion criteria:
Lack of consent to participate in the study Significant organ dysfunction Cutaneous malignancies Generalized eczema Pregnant or breastfeeding women Women of childbearing age who do not use adequate contraception Inability to adhere to treatment or attend regular follow-up visits
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a completely randomized block design was used. To allocate patients to the treatment and control groups, a randomized permuted block method was applied. Blocks were defined according to eczema severity (mild, moderate, and severe), and allocation within each block was performed randomly. Patients were enrolled in the study voluntarily after signing an informed consent form. At the first visit, demographic information (age and sex), eczema severity based on the Eczema Area and Severity Index (EASI), Scoring Atopic Dermatitis (SCORAD), pruritus based on the Visual Analog Scale (VAS), and skin-related quality of life using the Dermatologic Life Quality Index (DLQI) were collected. Then, patients were assigned using the randomized permuted block method into three groups according to eczema severity (mild, moderate, and severe). These three groups included two experimental groups and one control group, with allocation performed using simple randomization.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study was conducted as a single-blind trial, in which only the participants were unaware of the type of treatment they received (oral curcumin, topical curcumin, or placebo). The treatment staff and outcome assessors were aware of the patients' treatment allocation. This blinding method was applied to reduce the subjective influence of participants on outcome assessment and to enhance the validity of the collected data.
Placebo
Used
Assignment
Parallel
Other design features
The present study is a cross-sectional, single-blind, placebo-controlled clinical trial, which can be considered applied based on its objectives.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Ghasrodasht Street, Alley 3 Vali Asr, Sub-alley 3/2
City
Shiraz
Province
Fars
Postal code
۷۱۸۳۸۹۶۴۰۱۷
Approval date
2025-04-22, 1404/02/02
Ethics committee reference number
31423

Health conditions studied

1

Description of health condition studied
Eczema
ICD-10 code
L20.84
ICD-10 code description
Intrinsic (allergic) eczema

Primary outcomes

1

Description
Eczema severity
Timepoint
Data were collected and analyzed at baseline and after two weeks and four weeks of treatment
Method of measurement
Assessed using the Eczema Area and Severity Index (EASI) or Scoring Atopic Dermatitis (SCORAD)

2

Description
Pruritus severity
Timepoint
Data were collected and analyzed at baseline and after two weeks and four weeks of treatment
Method of measurement
Assessed using the Visual Analog Scale (VAS)

3

Description
Skin-related quality of life
Timepoint
Data were collected and analyzed at baseline and after two weeks and four weeks of treatment
Method of measurement
Assessed using the Dermatologic Life Quality Index (DLQI)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:1:Oral curcumin: Abureyhan curcumin capsules 500 mg, administered at a dose of 1000 mg per day (two 500 mg capsules)
Category
Treatment - Drugs

2

Description
Intervention group:2:Topical curcumin: Sinacurcumin nanomicelle soft gel 80 mg, applied twice daily to the lesions.
Category
Treatment - Drugs

3

Description
Control group: Two placebos were used simultaneously: oral placebo (tablet, once daily) and topical placebo (cold cream, applied twice daily to the lesions).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Asthma and Allergy Clinic, Shiraz
Full name of responsible person
ElhamAmini
Street address
Shiraz, Namazi Square, next to the Blood Transfusion Center
City
Shiraz
Province
Fars
Postal code
۷۱۳۴۸۱۴۷۳۴
Phone
+98 71 3212 7001
Email
emamreza@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
Street address
Zand Street, Central Building of Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
۷۱۳۴۸۱۴۳۳۶
Phone
+98 71 3212 2430
Email
vcrdep@sums.ac.ir
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
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Elham Amini

Position
Clinical Allergy and Immunology Fellow
Latest degree
Subspecialist
Other areas of specialty/work
Immunology
Street address
No.3,Valiasr alley,Ghasrodasht Ave
City
Shiraz
Province
Fars
Postal code
۷۱۸۳۸۹۶۵۱۷
Phone
+98 71 3628 0318
Fax
Email
amini.elham9170@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Elham Amini
Position
Clinical Allergy and Immunology Fellow
Latest degree
Subspecialist
Other areas of specialty/work
Immunology
Street address
No.3,Valiasr alley,Ghasrodasht Ave
City
Shiraz
Province
Fars
Postal code
۷۱۸۳۸۹۶۵۱۷
Phone
+98 71 3628 0318
Fax
Email
amini.elham9170@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Elham Amini
Position
Clinical Allergy and Immunology Fellow
Latest degree
Subspecialist
Other areas of specialty/work
Immunology
Street address
No.3,Valiasr alley,Ghasrodasht Ave
City
Shiraz
Province
Fars
Postal code
۷۱۸۳۸۹۶۵۱۷
Phone
+98 71 3628 0318
Fax
Email
amini.elham9170@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Comparison of the Therapeutic Effects of Oral and Topical Curcumin in Patients with Eczema and Its Evaluation Compared with Placebo in Patients Attending Imam Reza Clinic, Shiraz, During 2024–2025
When the data will become available and for how long
Six months after the publication of the results
To whom data/document is available
The data will only be accessible to authorized individuals related to the study, including the principal investigator, authors, advisors, reviewers, relevant staff, and researchers affiliated with the relevant academic and scientific institutions
Under which criteria data/document could be used
The data may only be used if a favorable outcome indicating improvement of skin eczema is achieved and approved by the Food and Drug Administration
From where data/document is obtainable
The data can be obtained from the supervisors,investigator and author associated with the study: Principal supervisor of the study:Dr.Seyed Hesam Nabavi Zadeh,Contact number: 0098917 111 0867 Study investigator and author: Dr. Elham Amini, Contact number:00989360903621
What processes are involved for a request to access data/document
1. Submission of a written request to the principal investigator stating the reason for requesting the data and the extent of the data needed. 2. Completion of the study data request form. 3. Review of the request by the principal investigator. 4. Approval or rejection of the request. 5. If approved, establishing contact between the

applicant and the study investigator. 6. Completion of a guarantee form confirming the non-disclosure of the data

Comments