Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of a platelet-rich topical formulation in the treatment of hand eczema: A pilot clinical trial study

Protocol summary

Study aim
To evaluate the effectiveness and safety of a platelet-rich topical formulation (PRP) for the treatment of hand eczema

Design
A non-randomized controlled pilot clinical trial with parallel groups, double-blinded, conducted on 80 patients (40 participants per group).

Settings and conduct
This study will be conducted at Dr. Torabizadeh's Clinic and Dr. Saki's Laboratory in Ahvaz, Iran. Eligible patients will be screened at Dr. Torabizadeh's Clinic and will be enrolled in the study using a non-randomized method. They will subsequently undergo examination, treatment, and follow-up at the clinic. The platelet-rich plasma (PRP)-enriched topical formulation will be prepared according to the study protocol under sterile conditions at Dr. Saki's Laboratory and then transferred to the clinic for patient treatment. The study will be conducted in a double-blind manner.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Clinical diagnosis of eczema (atopic dermatitis) confirmed by a dermatologist, Age between 18 and 65 years, Mild to moderate disease severity based on validated clinical scoring systems, Written informed consent to participate in the study, Exclusion criteria: Presence of other inflammatory or autoimmune skin diseases, Pregnancy or breastfeeding, Severe systemic diseases (hepatic, renal, cardiac disorders, or malignancies), Active skin infection at the study site

Intervention groups
Intervention Group: Participants will receive an autologous topical formulation containing PRP and albumin. PRP will be prepared by two-step centrifugation, combined with albumin, and applied once daily for 7–10 days. Control Group: Participants will receive a placebo base cream without PRP or albumin, identical in appearance and application method, once daily for 7–10 days.

Main outcome variables
Hand Eczema Severity Index (HECSI) Score

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20251122068073N2**
Registration date: **2026-08-21, 1405/05/30**
Registration timing: **retrospective**

Last update: **2026-08-21, 1405/05/30**
Update count: **0**

Registration date
2026-08-21, 1405/05/30

Registrant information
Name
Mehdi Totabizadeh
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-01-04, 1404/10/14
Expected recruitment end date
2026-04-19, 1405/01/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of a platelet-rich topical formulation in the treatment of hand eczema: A pilot clinical trial study

Public title
Evaluation of a platelet-rich topical formulation in the treatment of hand eczema

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Clinical diagnosis of eczema (atopic dermatitis) confirmed by a dermatologist Age between 18 and 65 years Mild to moderate disease severity based on validated clinical scoring systems Written informed consent to participate in the study

Exclusion criteria:
Presence of other inflammatory or autoimmune skin diseases Pregnancy or breastfeeding Severe systemic diseases (hepatic, renal, cardiac disorders, or malignancies) Active skin infection at the study site

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted using a double-blind design. Participants will be informed during the informed consent process that the study includes two groups (a topical PRP-albumin formulation and a placebo base cream) and that they will be randomly assigned to one of the groups; however, they will remain unaware of their treatment allocation. The placebo will be identical to the intervention in appearance, color, consistency, packaging, and method of application. The randomization sequence will be generated using the Sealed Envelope online system, and allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes. Investigators, outcome assessors, and the statistical analyst will remain blinded to treatment allocation until completion of the data analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahvaz Jundishapur University of Medical Sciences Ethics Committee

Street address
Ethics Committee Office, First Floor, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, University Campus, Golestan

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2025-11-01, 1404/08/10

Ethics committee reference number
IR.AJUMS.REC.1404.405

Health conditions studied

1

Description of health condition studied
eczema

ICD-10 code
L30.9

ICD-10 code description
Dermatitis, unspecified

Primary outcomes

1

Description
Hand Eczema Severity Index (HECSI) Score

Timepoint
The assessment is once before the intervention and once after the formulation is consumed.

Method of measurement
The severity of hand eczema is measured using the Hand Eczema Severity Index. In this index, clinical symptoms including redness, scaling, vesicles, fissures, edema, and papules in different areas of the hand (palms, back of the hand, and fingers) are assessed by a physician and scored based on the severity of each symptom and the extent of involvement.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: Participants in the intervention group will receive an autologous topical formulation containing platelet-rich plasma (PRP) and autologous albumin. PRP will be prepared using a two-step centrifugation method and mixed at a ratio of 2/3 PRP to 1/3 autologous albumin. The formulation will be applied topically once daily for 7–10 days to the affected area. Clinical assessment will be performed before and after the treatment period.

Category
Treatment - Drugs

2

Description
Control group: Participants in the control group will receive a placebo base cream without PRP or albumin, identical to the intervention formulation in appearance, consistency, and method of application. The placebo cream will be applied topically once daily for 7–10 days to the affected area. Clinical assessment will be performed before and after the treatment period.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr Torabizadeh's office

Full name of responsible person
Mehdi Torabizadeh

Street address
Arad Medical Complex, East 17th Street, Kianpars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Mehdi Torabizadeh

Position
associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Immunology

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Associate professor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available