Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Oct 2026

Efficacy of 5% caffeine plus 0.025% Fluocinolone acetonide versus 0.025% Fluocinolone acetonide alone for topical treatment of chronic plaque psoriasis

Protocol summary

Study aim
Evaluating the efficacy of 5% caffeine plus 0.025% Fluocinolone acetonide versus 0.025% Fluocinolone acetonide alone for topical treatment of chronic plaque psoriasis

Design
Randomized phase 3, triple-blinded clinical trial with parallel-groups on 40 patients.

Settings and conduct
40 patients who had consecutively presented to the university's outpatient dermatology clinic with typical manifestations of plaque psoriasis and had not used topical medications for two weeks before the study, to minimize selection bias, the patients will randomly assigned to one of two treatment groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria were patient age over 7 years, no history of immunosuppression or iatrogenic, not using medication or treatment methods to treat psoriasis in the two weeks before the study, no history of caffeine allergy, not pregnant or currently breastfeeding, and consent to participate in the study. Exclusion criteria were pregnant or lactating women, aggravation of the disease during the study, joint involvement during the study that requires oral treatment, and sensitization while using the drug during the study (such as vesicular rash, erythema, itching, etc.)

Intervention groups
Intervention group 1: Patients will receive the prepared cream containing 5% caffeine along with fluocinolone acetonide 0.025%. The creams are distributed in divided doses at the beginning and at the second weekly assessment. The amount of cream used is such that it covers the lesion completely. Intervention group 2: Patients will receive the prepared cream containing fluocinolone acetonide 0.025%. The creams are distributed in divided doses at the beginning and at the second weekly assessment. The amount of cream used is such that it covers the lesion completely.

Main outcome variables
The rate of recovery of lesions

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091012002581N10**
Registration date: **2023-10-28, 1402/08/06**
Registration timing: **prospective**

Last update: **2023-10-28, 1402/08/06**
Update count: **0**

Registration date
2023-10-28, 1402/08/06

Registrant information

Name
Hamide Herizchi

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-11-22, 1402/09/01

Expected recruitment end date
2024-03-20, 1403/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficacy of 5% caffeine plus 0.025% Fluocinolone acetonide versus 0.025% Fluocinolone acetonide alone for topical treatment of chronic plaque psoriasis

Public title
Comparing the efficacy of 0.025% Fluocinolone acetonide with and without 5% caffeine in topical treatment of chronic plaque psoriasis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient age over 7 years No history of immunosuppression or iatrogenic Not using medication or treatment methods to treat psoriasis in the two weeks before the study No history of caffeine allergy Not pregnant or currently breastfeeding Consent to participate in the study
Exclusion criteria:
Pregnant or lactating women Aggravation of the disease during the study Joint involvement during the study that requires oral treatment Sensitization while using the drug during the study (such as vesicular rash, erythema, itching, etc.)
Age
From **7 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be using sealed envelopes, of which 40 envelopes will be selected in total and will be divided into two groups of 20, including groups A and B. Envelopes will be selected by the operating room nurse who is blind to the study groups. Group A will be the intervention 1 group, group B will be the intervention 2 group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The attending physician and patients will not be informed of the type of drug combination received and the list of drugs received by each patient will be provided to the patient and the researcher responsible for data collection in the form of a sealed envelope.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice Chancellor for research of Tabriz Univercity of Medical Sciences
Street address
Vice Chancellor for research, 3rd floor, central office, Tabriz Univercity of Medical Sciences, Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
515431232
Approval date
2023-08-07, 1402/05/16
Ethics committee reference number
IR.TBZMED.REC.1402.342

Health conditions studied

1

Description of health condition studied
Chronic plaque psoriasis
ICD-10 code
L40
ICD-10 code description
Psoriasis

Primary outcomes

1

Description
The rate of recovery of lesions
Timepoint
Patients will be evaluated at the beginning of the study and at weekly intervals for three consecutive weeks.
Method of measurement
Psoriasis area and severity index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients will receive the prepared cream containing 5% caffeine along with fluocinolone acetonide 0.025%. The creams are distributed in divided doses at the beginning and at the second weekly assessment. The amount of cream used is such that it covers the lesion completely.
Category
Treatment - Drugs

2

Description
Intervention group 2: Patients will receive the prepared cream containing fluocinolone acetonide 0.025%. The creams are distributed in divided doses at the beginning and at the second weekly assessment. The amount of cream used is such that it covers the lesion completely.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Dr Hamideh Herizchi-Ghadim
Street address
Maralan street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Drherizchi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Hamideh Herizchi Ghadim
Position
Dermatologist Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position

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Latest degree
Specialist
Other areas of specialty/work
Dermatology
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Person responsible for updating data

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Web page address

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
No - There is not 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
Study data is categorized and coded with no identifiable individuals.
When the data will become available and for how long
Access to study data after publication of the result is available in the journal.
To whom data/document is available
Anyone interested in using the data can access the study data.
Under which criteria data/document could be used
Study data can be used for comparison with other results.
From where data/document is obtainable
Refer to the study's scientific or public accountability person for data.
What processes are involved for a request to access data/document
The request will be sent by email to person responsible for scientific or public inquiries.
Comments