

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 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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+98 41 1336 4650

Email address

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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 University of Medical Sciences

Street address

Vice Chancellor for research, 3rd floor, central office, Tabriz University of Medical Sciences, Tabriz

City

Tabriz

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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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Tabriz

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5163639888

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+98 41 3541 2101

Email

Drherizchi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ataa Mahmoudpour

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5163639888

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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

Contact

Name of organization / entity

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Full name of responsible person

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Position

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

Contact

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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