

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparative Study between Efficacy of Tofacitinib Niosomal 2% Lotion versus Clobetasol 0.01% Lotion in Alopecia Areata

Protocol summary

Study aim

Determining the Effectiveness of Treatment with 2% Tofacitinib Niosomal Lotion Compared to 0.01% Clobetasol Lotion in the Treatment of Patients with Alopecia Areata

Design

The Clinical Phase of This Study Will Be Conducted as a Randomized, Double-Blind Clinical Trial on 40 Patients with Patchy Scalp Alopecia Areata at Afzalipour Hospital, Kerman in 2024. The Aim Is to Initially Evaluate the Efficacy and Safety Of 2% Tofacitinib Niosomal Lotion Compared to 0.01% Clobetasol. The Diagnosis of the Disease Will Be Made by a Dermatologist. Patients will be Divided into Two Groups Using a Block Randomization Method and Will Apply the Lotions to the Alopecia Patches Twice Daily For 12 Weeks.

Settings and conduct

This Study is a Double-Blind Clinical Trial (Analyst and Evaluator are Unaware of the Type of Treatment) on Patients with Patchy Alopecia Areata Referred to Afzalipour Hospital in Kerman in 1404.

Participants/Inclusion and exclusion criteria

Entry requirements: Age Equal to or Greater Than Four Years, Alopecia Areata Patchy Form (SALT \leq 25%), Not Using Other Hair Loss Treatments in the Past Three Months, Ability and Willingness to Follow Instructions for Using Lotions, Normal Tests Include: CBC, Creatinine, Liver Tests, Thyroid Tests, Anti-Thyroperoxidase and Thyroglobulin Antibodies, and FBS Exit requirements: History of Autoimmune Diseases and Use of Biological Therapies and Immunosuppressants Within the Past 6 Months Use of Topical Corticosteroids in the Past Month at the Site Pregnancy, Breastfeeding Phototherapy within the past 3 Months Thyroid Dysfunction and Cytopenia

Intervention groups

The First Group is Treated With 2% Tofacitinib Niosomal Lotion and the Second Group is Treated with 0.01% Clobetasol Lotion.

Main outcome variables

Hair Loss Treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251010067571N1**

Registration date: **2025-10-18, 1404/07/26**

Registration timing: **registered_while_recruiting**

Last update: **2025-10-18, 1404/07/26**

Update count: **0**

Registration date

2025-10-18, 1404/07/26

Registrant information

Name

Banafshe Farzadfard

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5419

Email address

banafshefrzd@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-16, 1404/07/24

Expected recruitment end date

2026-03-19, 1404/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Study between Efficacy of Tofacitinib Niosomal 2% Lotion versus Clobetasol 0.01% Lotion in Alopecia Areata

Public title

Efficacy of Treatment with 2% Tofacitinib Niosomal Lotion Compared to 0.01% Clobetasol Lotion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age Equal to or Greater Than Four Years Alopecia Areata Patchy Form (SALT \leq 25%) Not Using Other Hair Loss Treatments in the Past Three Months Ability and Willingness to Follow Instructions for Using Lotions Normal Tests Include: CBC, Creatinine, Liver Tests, Thyroid Tests, Anti-Thyroperoxidase and Thyroglobulin Antibodies, and FBS

Exclusion criteria:

History of Autoimmune Diseases and Use of Biological Therapies and Immunosuppressants Within the Past 6 Months Use of Topical Corticosteroids in the Past Month at the Site Pregnancy, Breastfeeding Phototherapy within the past 3 Months Thyroid Dysfunction Cytopenia (Leukocytes $> 3 \times 10^9$, Lymphocytes $> 0.8 \times 10^9$, Neutrophils $<$ Lower Limit of Normal Range, Hemoglobin < 10 g/dl, Platelets $< 100 \times 10^9$)

Age

From 4 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

The Unit Randomization Is Performed in A Block Method with a Block Size Of 4. For Each of the 6 Possible Cases for the Block of 4, The Numbers Are Assigned as Follows: ABBA(3), ABAB(2), AABB(1), BAAB(6), BABA(5), BBAA(4) with the Help of a Random Number Table, Numbers Between 1 And 6 Are Selected and the Treatment Allocation List Is Determined According to Each Number. To Implement the Generated Random Sequence, The Method of Concealing Coded Boxes or Cans Is Used. In This Method, The Cans are Numbered based on a Random Sequence and Inside the Boxes, The Desired Intervention (Drug) or a Sheet on Which the Random Assignment Is Written Is Provided to the Executor, Provided That the Boxes Are Completely Sealed, and the Researcher Allocates Them to the Intervention and Standard Treatment Groups Based on the Order of Patients' Arrival. Tool: Creating A Random Sequence of 4-

Block Randomization Concealment Will Be Performed to Implement the Random Sequence on the Study Participants. Construction: Randomly Select the Block and Read the Letters from Right to Left. Concealment Will Be Done Using Cans That Are Numbered in a Random Sequence. The Cans Will Have the Same Weight and Shape and Will Be Prepared by an Independent Researcher.

Blinding (investigator's opinion)

Double blinded

Blinding description

The Study is Conducted in a Double-Blind, Randomized Manner; The Patient and the Evaluating Physician are Unaware of the Treatment Type (Tofacitinib Niosomal 2% Or Clobetasol 1%). The Drugs are Standardized in Appearance, Color, And Packaging, and Each Package Is Identified by a Confidential Random Code. The List of Codes Is Kept by the Responsible Pharmacist and Can Only Be Opened in Cases of Medical Emergency

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Afzalipour Hospital-Kerman University of Medical Sciences

Street address

Afzalipour Hospital, Emam Khomeini Blvd.

City

Kerman

Province

Kerman

Postal code

7616913355

Approval date

2025-09-27, 1404/07/05

Ethics committee reference number

IR.KMU.AH.REC.1404.131

Health conditions studied

1

Description of health condition studied

Alopecia areata

ICD-10 code

L63

ICD-10 code description

Alopecia areata

Primary outcomes

1

Description

Hair Loss Treatment

Timepoint

12 Weeks

Method of measurement

Measuring the Percentage of Hair Loss with SALT Score, Regrowth Rate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first Group was Treated with 2% Tofacitinib Niosomal Lotion

Category

Treatment - Drugs

2

Description

Intervention group: The second Group was Treated with 0.01% Clobetasol Lotion

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Banafshe Farzadfard

Street address

Afzalipour Hospital, Emam Khomeini Blvd.

City

Kerman

Province

Kerman

Postal code

7616913355

Phone

+98 34 3132 8328

Email

banafshefrzd@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Banafshe Farzadfard

Street address

Afzalipour Hospital, Emam Khomeini Blvd.

City

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Province

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Postal code

7616913355

Phone

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Email

banafshefrzd@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Banafshe Farzadfard

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not 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

Title and more details about the data/document

Data on the Main Outcomes of the Research after the Completion of Research Work Can be Published.

When the data will become available and for how long

Starting Access to the Data above is Immediately after Publishing the Results.

To whom data/document is available

Researchers in Academia and Scientific Institute are Able to Access Research Data.

Under which criteria data/document could be used

In Case of Supplementary Research, Using Data is Permitted.

From where data/document is obtainable

The Applicant Can Contact the Researcher to Receive Information Via Email.

What processes are involved for a request to access data/document

After Submitting a Written Request from the Applicant, The Data Will Be Provided to Him/Her as soon as Possible.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Banafshe Farzadfard

Position

Resident

Latest degree

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Other areas of specialty/work

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