Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 ≤ 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 ≤ 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 × 10^9, Lymphocytes > 0.8 × 10^9, Neutrophils < Lower Limit of Normal Range, Hemoglobin < 10 g/dl, Platelets < 100 × 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
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Postal code
7616913355
Phone
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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
Kerman
Postal code
7616913355
Phone
+98 34 3132 8328
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
Afzalipour Hospital, Emam Khomeini Blvd.
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Person responsible for scientific 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
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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
Medical doctor

Other areas of specialty/work
Dermatology

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Afzalipour Hospital, Emam Khomeini Blvd.

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Postal code
7616913355

Phone
+98 34 3132 8328

Email
banafshefrzd@gmail.com

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