Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Efficacy of Oral Tofacitinib and Oral Prednisolone in moderate to severe Alopecia Areata - A comparative study

Protocol summary

Study aim
This study aims to compare efficacy of oral tofacitinib with oral prednisolone in treatment of moderate to severe Alopecia Areata

Design
Randomized, parallel double blinded study

Settings and conduct
Participants meeting the inclusion criteria will be allocated into two groups by lottery method of randomization. Prior to start of medication SALT score, digital photographs and Laboratory tests will be done. Group A will receive oral Tofacitinib 5 mg (twice daily)' for three months, Group B will receive oral Prednisolone 0.5 mg/Kg for 6 Weeks and then tapered very slowly over next six weeks for three months. Participants will be blinded to what treatment they are getting. Regrowth will be assessed using photographic assessment and salt score at Week 2, 6, 10 and 12 Weeks. Laboratory tests will be repeated monthly. Any adverse effect, recurrence and compliance will also be documented. Study will be conducted at CMH Quetta, Pakistan.

Participants/Inclusion and exclusion criteria
Inclusion criteria: clinical diagnosis of alopecia areata with SALT score of 25 % or more; age 15-59 years old; no other treatment for AA taken in last 3 months. Exclusion criteria: history of severe systemic diseases (Hepatic, renal, pulmonary and cardiovascular); pregnant or lactating mother. Those with other causes of hair loss; androgenetic alopecia, telogen effluvium, trichotillomania and cicatricial alopecia. Hypersensitivity to medications. Patients who are immunodeficient or undergoing immunosuppressive therapy.

Intervention groups
Group A: Oral Tofacitinib 5 mg (twice daily)' for three months. Group B: Oral Prednisolone 0.5 mg/Kg for 6 Weeks and then tapered slowly over next six weeks

Main outcome variables
Outcome will be ascertained on the basis of reduction in Severity of Alopecia Tool (SALT) score from base line, Photographic assessment and laboratory tests.

General information

Reason for update

Acronym
AA Alopecia Areata

IRCT registration information
IRCT registration number: **IRCT20210823052264N12**
Registration date: **2024-12-19, 1403/09/29**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-19, 1403/09/29**
Update count: **0**

Registration date
2024-12-19, 1403/09/29

Registrant information

Name
Najia Ahmed

Name of organization / entity
PNS shifa

Country
Pakistan

Phone
+92 81 2864092

Email address
najiaomer@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-13, 1403/09/23

Expected recruitment end date
2025-03-13, 1403/12/23

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Oral Tofacitinib and Oral Prednisolone in moderate to severe Alopecia Areata - A comparative study

Public title

Efficacy of Oral Tofacitinib and Oral Prednisolone in moderate to severe Alopecia Areata - A comparative study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinical diagnosis of alopecia areata with SALT score of 25 % or more Age Range 15-59 years Patients who have not taken oral, topical or systemic treatment for alopecia areata within 3 months prior to study

Exclusion criteria:

History of severe systemic diseases (Hepatic, renal, pulmonary and cardiovascular) Pregnant or nursing mother Those with other causes of hair loss; androgenetic alopecia, telogen effluvium, trichotillomania and cicatricial alopecia Hypersensitivity to medications Patients who are immunodeficient or undergoing immunosuppressive therapy

Age

From **15 years** old to **59 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with lottery method using sealed envelope

Blinding (investigator's opinion)

Double blinded

Blinding description

Double blinded study (Participants and data analyzer are blinded)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional Ethical Review Board (IERB) certificate - CMH Quetta

Street address

Quetta Cantt

City

Quetta

Postal code

08762

Approval date

2024-12-13, 1403/09/23

Ethics committee reference number

CMH QTA-IERB/57/2024

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

Change in SALT score from baseline

Timepoint

Before intervention, 2, 6,10 and 12th week

Method of measurement

Clinical Examination and recording SALT score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A will be given Tofacitinib 5 mg (twice daily) for three months

Category

Treatment - Drugs

2

Description

Intervention group: Group B Patients will receive oral prednisolone 0.5 mg/Kg for 6 weeks and then tapered very slowly over next 6 weeks

Category

Treatment - Drugs

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Combined Military Hospital, Quetta, Pakistan
Full name of responsible person
RABBIA TARIQ
Street address
Quetta Cantt
City
Quetta
Postal code
08762
Phone
+92 335 0244445
Fax
Email
rabbiaadil15@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Combined Military Hospital, Quetta, Pakistan
Full name of responsible person
RABBIA TARIQ
Street address
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City
Quetta
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08762
Phone
+92 335 0244445
Fax
Email
rabbiaadil15@gmail.com
Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Combined Military Hospital, Quetta, Pakistan

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

Person responsible for general inquiries

Contact

Name of organization / entity
Combined Military Hospital, Quetta, Pakistan
Full name of responsible person
RABBIA TARIQ
Position
Resident
Latest degree
Subspecialist
Other areas of specialty/work
Dermatology
Street address
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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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