

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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

Quetta Cantt

City

Quetta

Postal code

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

Quetta Cantt

City

Quetta

Province

Balochistan

Postal code

08762

Phone

+92 335 0244445

Fax**Email**

rabbiaadil15@gmail.com

Web page address**Person responsible for scientific 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

Quetta Cantt

City

Quetta

Province

Balochistan

Postal code

08762

Phone

+92 335 0244445

Fax**Email**

rabbiaadil15@gmail.com

Web page address**Person responsible for updating data****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

Quetta Cantt

City

Quetta

Province

Balochistan

Postal code

08762

Phone

+92 335 0244445

Fax**Email**

rabbiaadil15@gmail.com

Web page address**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