

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Efficacy and safety of Tofacitinib versus Azathioprine in severe alopecia areata, alopecia universalis and alopecia totalis.

Protocol summary

Study aim

To evaluate the efficacy and safety of tofacitinib vs azathioprine for the treatment of severe Alopecia areata, Alopecia totalis and Alopecia universalis.

Design

randomized, paralld, double blinded study.

Settings and conduct

Dermatology Department, Lady Reading Hospital Peshawar, Pakistan. Care givers, participants, investigators and outcome assessors will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 1. Patients with >12 years to <60 years age 2. Patients having alopecia areata with $\geq 50\%$ scalp hair loss, alopecia totalis and alopecia universalis. 3. Stable or worsening disease for ≥ 6 months 4. Patients must not have received any treatments for the disease under study within 2 months of enrollment and will not be permitted to use any other treatment known to affect the disease under study for the duration of treatment. Exclusion Criteria: Following patients will be excluded if they had 1. Active malignancy or a history of malignancy 2. Leukopenia, Anemia 3. Hepatic or renal impairment, 4. Human immunodeficiency virus, Hepatitis B and C. 5. Patients taking systemic immunomodulatory medications 6. Pregnant or nursing women 7. Women of childbearing age who are unwilling or unable to use contraception

Intervention groups

Patients in group A will receive tofacitinib at 5mg twice daily for 6 months and patients in group B will receive azathioprine in an oral dose of 1-2 mg/kg/day for 6 months.

Main outcome variables

The outcome will be percent change in Severity of Alopecia Tool (SALT) score, calculated by dividing the absolute change in SALT score from the time of treatment initiation to the last evaluation by the initial SALT score. Percent change in SALT score of 100% indicates complete hair regrowth, whereas 0% indicates no regrowth. Treatment will be considered efficacious if

percent change in SALT score is > 50%.

General information

Reason for update

no reason

Acronym

TAA

IRCT registration information

IRCT registration number: **IRCT20220904055876N1**

Registration date: **2022-09-20, 1401/06/29**

Registration timing: **prospective**

Last update: **2022-10-29, 1401/08/07**

Update count: **1**

Registration date

2022-09-20, 1401/06/29

Registrant information

Name

Farah Sagheer

Name of organization / entity

Lady Reading Hospital Peshawar Pakistan

Country

Pakistan

Phone

+92 321 9049707

Email address

farah.sagheer@lrh.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-04, 1401/07/12

Expected recruitment end date

2023-03-04, 1401/12/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy and safety of Tofacitinib versus Azathioprine in severe alopecia areata, alopecia universalis and alopecia totalis.

Public title

Tofacitinib and azathioprine in alopecia areata

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients having Alopecia areata with $\geq 50\%$ scalp hair loss, Alopecia totalis and Alopecia universalis. Patients must not have received any treatments for Alopecia areata within 2 months of enrollment and will not permitted to use any other treatment known to affect AA Stable or worsening disease for ≥ 6 months

Exclusion criteria:

Active malignancy or a history of malignancy
Leukopenia, Anemia Hepatic or renal impairment Human immunodeficiency virus, Hepatitis B and C. Pregnant or nursing women

Age

From **12 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Method: Block randomization Unit: individual Tolls: computer softwares double blinded Randomization will be 1:1 for group A and group B, i.e., each upcoming patient will be included in the next group.

Blinding (investigator's opinion)

Double blinded

Blinding description

participants, care provider, investigator and outcome assessor were blinded. Tablets with same appearance, odor, taste, texture and color but different active substance were used. Only drug manufacturing company was aware of active substance.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Lady Reading Hospital Peshawar

Street address

Dermatology Department, Lady Reading Hospital
Peshawar, Pakistan.

City

Peshawar

Postal code

45666

Approval date

2022-08-10, 1401/05/19

Ethics committee reference number

458/LRH/MTI

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**

Severity of Alopecia Tool (SALT) score. Treatment will be considered efficacious if percent change in SALT score is $> 50\%$.

Timepoint

before intervention and 3 months and 6 months after intervention

Method of measurement

Severity of Alopecia Tool (SALT) score

Secondary outcomes

empty

Intervention groups**1****Description**

Patients in group A will receive tofacitinib at 5mg twice daily for 6 months and patients in group B will receive azathioprine in an oral dose of 1-2 mg/kg/day for 6 months

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Lady Reading Hospital Peshawar, Pakistan

Full name of responsible person

Farah Sagheer

Street address

Lady Reading Hospital Peshawar Pakistan

City

Peshawar

Postal code

45666

Phone

+92 321 9049707

Email

farah.sagheer@lrh.edu.pk

Web page address

<https://pubmed.ncbi.nlm.nih.gov/21616562/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Lady Reading Hospital Peshawar Pakistan

Full name of responsible person

Farah Sagheer

Street address

Lady Reading Hospital Peshawar Pakistan

City

Peshawar

Postal code

45666

Phone

+92 321 9049707

Email

farah.sagheer@lrh.edu.pk

Grant name

Lady reading hospital peshawar

Grant code / Reference number

6677

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

Yes

Title of funding source

Lady Reading Hospital Peshawar 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

Lady Reading Hospital Peshawar Pakistan

Full name of responsible person

Farah Sagheer

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Lady Reading Hospital, Peshawar, Pakistan

City

Peshawar

Province

Khyber pukhtunkhwa

Postal code

45666

Phone

+92 321 9049707

Fax

Email

farah.sagheer@lrh.edu.pk

Person responsible for scientific inquiries

Contact

Name of organization / entity

Lady Reading Hospital Peshawar Pakistan

Full name of responsible person

Farah Sagheer

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Lady Reading Hospital, Peshawar, Pakistan

City

Peshawar

Province

Khyber pukhtunkhwa

Postal code

45666

Phone

+92 321 9049707

Fax

Email

farah.sagheer@lrh.edu.pk

Person responsible for updating data

Contact

Name of organization / entity

Lady Reading Hospital Peshawar Pakistan

Full name of responsible person

Farah Sagheer

Position

Consultant

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

Street address

Lady Reading Hospital, Peshawar, Pakistan

City

Peshawar

Province

Khyber pukhtunkhwa

Postal code

45666

Phone

+92 321 9049707

Fax**Email**

farah.sagheer@lrh.edu.pk

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

Yes - There is 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

Efficacy and safety of Tofacitinib versus Azathioprine in severe alopecia areata, alopecia universalis and alopecia totalis.

When the data will become available and for how long

6 months after publication

To whom data/document is available

for people working in academic institutions

Under which criteria data/document could be used

no criteria

From where data/document is obtainable

contact via email provided previously

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

no process involved

Comments

none