

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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, paralalled, 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  $\geq 6$  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 be permitted to use any other treatment known to affect AA. Stable or worsening disease for  $\geq 6$  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. Tool: computer software. 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**

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**Phone**

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**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

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**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**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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**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