Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 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, paralled, 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.Pateints with >12 years to <60 years age 2. Patients having alopecia areata with ≥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

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+92 321 9049707

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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 ≥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: indiviual 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

Treatment - Drugs

Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Lady Reading Hospital Peshawar, Pakistan

Full name of responsible person
Farah Sagheer

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

Sponsors / Funding sources

1

Sponsor

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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

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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