

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison between intralesional triamcinolone acetonide plus tacrolimus and tacrolimus alone in young patient with alopecia areata

Protocol summary

Study aim

The objective is to evaluate the effectiveness of combined treatment with triamcinolone acetonide and I/L plus tacrolimus versus tacrolimus alone in young patients with AA ,the study aims to compare clinical outcomes ,including symptoms resolution,improvement in hair fall & patient satisfaction between the two treatment regimens.

Design

Community-based ,parallel group .non blind ,randomized controlled trial.

Settings and conduct

This study will be conducted on patients presenting in dermatology OPD fulfilling the inclusion criteria and study is not blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria for the study are diagnosed cases of alopecia areata,patient age between 12-50 years of either sex,those willing to provide informed consent. Patient diagnosed with alopecia areata. Exclusion Criteria include ,patient having SALT score < 50 at baseline. Non-consenting patient. Patient with autoimmune diseases. Pregnant women. Patient's on immunosuppression therapy.

Intervention groups

All patient will be randomly divided into 2 groups by using sequentially numbered opaque envelop. Patient in group A will receive intralesional triamcinolone Acetonide with topical tacrolimus 0.1% while group B will receive topical tacrolimus 0.1%. In group A, intralesional triamcinolone Acetonide 10mg will be given every 3 weeks along with topical tacrolimus 0.1% twice a day for 12 weeks. In group B, topical tacrolimus 0.1% will be advise twice a day for 12 weeks.

Main outcome variables

Final outcome efficacy will be evaluated after 12 weeks of treatment by using SALT score as per criteria mentioned in operational definition. All the findings confounding variables such as age, gender, residence

and duration of hair loss will be noted in a predesigned performa.Efficacy in intralesional triamcinolone Acetonide with tacrolimus groups was higher as compared to tacrolimus alone (53.33% vs 30%).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250308064975N1**

Registration date: **2025-05-20, 1404/02/30**

Registration timing: **registered_while_recruiting**

Last update: **2025-05-20, 1404/02/30**

Update count: **0**

Registration date

2025-05-20, 1404/02/30

Registrant information

Name

Irfan Shaikh

Name of organization / entity

Shaheed mohtarma benazir bhutto medical university larkana

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Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-24, 1403/10/04

Expected recruitment end date

2025-06-24, 1404/04/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between intralesional triamcinolone acetonide plus tacrolimus and tacrolimus alone in young patient with alopecia areata

Public title

Effectiveness of intralesional triamcinolone acetonide plus tacrolimus or tacrolimus alone in young patient with alopecia areata.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient age between 12-50 years of both genders.

Patient diagnosed with alopecia areata.

Exclusion criteria:

Patient having SALT score < 50 at baseline Patient with autoimmune diseases Pregnant women Patient's on immunosuppression therapy. Non-consenting patient

Age

From **12 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **138**

More than 1 sample in each individual

Number of samples in each individual: **69**

69 in each group of either sex

Randomization (investigator's opinion)

Randomized

Randomization description

All patient will be randomly divided into 2 groups by using sequentially numbered opaque envelop. Patient in group A will receive intralesional triamcinolone Acetonide with topical tacrolimus 0.1% while group B will receive topical tacrolimus 0.1%. In group A, intralesional triamcinolone.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Community based ,parallel group ,non blinded randomized controlled trial.

Secondary Ids

empty

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

Research and ethical review shaheed mohtarma benazir bhutto medical university larkana

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H52X+R45, shah nawaz bhutto rd ,larkana ,

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Approval date

2025-05-06, 1404/02/16

Ethics committee reference number

NO.SMBBMU/IRB/25

Health conditions studied**1****Description of health condition studied**

Alopecia areata (AA) is an autoimmune disorder. Patient presenting with hairless baldness together with healthy skin and conserved follicular ostia. Hairs with exclamations mark and a test of positive pull are done to confirm diagnosis . Yellow spots can be seen on dermoscopy. Spared white hairs; a pigment less regrowth. Disease diagnosis will be confirmed on histopathology which shows an infiltrated inflammation of small lymphocytes which surrounds the follicular bulb in anagen. involves the nonscarring permanent reduction of the hair leading to loss of hair from the scalp. AA can occur as a result of self limiting disease with multiple patchy hair loss , as a chronic illness with many patches reoccur & remitt over many years, or whole scalp hair loss or universal loss of terminal hair.

ICD-10 code

L63

ICD-10 code description

Alopecia areata

Primary outcomes**1****Description**

primary outcome in patients with alopecia areata after treatment with intralesional (I/L) triamcinolone and tacrolimus in a randomized clinical trial typically involves assessing hair regrowth. Using trichoscan that analyzes hair density, thickness, and regrowth and taking standardized photographs of the affected area at baseline and follow-up visits to visually assess hair regrowth. Hair regrowth scoring as SALT (Severity of Alopecia Tool) score.

Timepoint

Patient is assessed ,before intervention and at 3,6,9,12 weeks after intervension

Method of measurement

Score based on SALT can be calculated using the measurement of the total percentage of hairs that are lost in four areas of the scalp — In the rightside profile (it accounts for 18% of the total area in the scalp), the left side profile (which also accounts for 18% of the total area in the scalp), at the vertex areas (40% of the total area of the scalp), and the posterior (24% of the total area of the scalp), as shown in the figure below. By including total percentage of hairs that are lost in each area are multiplied by the regions relative area, one attains a composite score total i.e the Score of SALT. The regrowth of the hair can be achieved through decreasing the SALT score (e.g, The SALT score can be consider 0 if there is complete hair regrowth. There is a simple tool for the calculation of SALT score based on loss of hair in each of the above mentioned areas. Online SALT score is available to predict hair regrow with treatment .

Secondary outcomes

1

Description

Side effects. Monitoring & documenting adverse effects related to the treatment ,skin irritation,bleeding ,scaring,telangiectasia.

Timepoint

Patient will assessed at 3,6,9,12 weeks after intervension

Method of measurement

Patient self-report: patient will be asked to report any discomfort,such as skin irritation,dryness,or allergic reactions during follow up vists. Clinical observation:inspect the treated areas for signs of adverse reactions such as redness ,swelling or peeling. Efficacy will be assesed using the same parameters as the intervension group: improvement in clinical signs, presence of initially soft hairs regrow followed by pigmented hairs

Intervention groups

1

Description

Intervention Groups Record 1:Group A (Intervention Group) Intervention:Intralesional Triamcinolone Acetonide 10mg every 3 weeks + Topical Tacrolimus 0.1% twice a day for 12 weeks. Record 2: Group B (Control Group) Intervention:Topical Tacrolimus 0.1% twice a day for 12 weeks. Study Details. Randomization: Sequentially numbered opaque envelopes . Follow-up: 3, 6, 9, and 12 weeks. Outcome Evaluation: SALT score after 12 weeks . Confounding Variables: Age, gender, residence, and duration of hair loss.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research and ethical review commitee shaheed mohtarma benazir bhutto medical university larkana

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shaheed mohtarma benazir bhutto medical university larkana

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Shaheed mohtarma benazir bhutto medical university
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Full name of responsible person

Dr Irfan shaikh

Position

Consultant

Latest degree

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

COMPARISON BETWEEN INTRALESIONAL
TRIAMCINOLONE ACETONIDE PLUS TACROLIMUS AND
TACROLIMUS ALONE IN YOUNG PATIENT WITH ALOPECIA
AREATA. PERFORMA S.No: _____ MR No:

Group: Triamcinolone Acetonide with
topical tacrolimus Topical Tacrolimus Age:
_____(Years) Gender: Male Female Residence:
Urban Rural Duration of hair loss: _____ (Months)
Time Point Severity of Alopecia Tool (SALT) Score
Baseline 3rd Week 6th Week 9th Week 12th Week

When the data will become available and for how long

After 6 monyhs RCT ,for 4 years

To whom data/document is available

Primary investigator

Under which criteria data/document could be used

All patients in dermatology OPD according to operational
definition of alopecia areata fullfling the inclusion
criteria.

From where data/document is obtainable

Shaheed mohtarma Benazir Bhutto medical university
larkana

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

contact to primary investigator

Comments