Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
Street address
H52X+R45, shah nawaz bhutto rd ,larkana ,
City
Larkana
Postal code
77150
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 confrm diagnosis . Yellow spots can been 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 sach 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
Dilshad parveen

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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 larkana

Full name of responsible person
Dr Irfan shaikh

Position
Consultant

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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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