Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative Efficacy of Different Concentrations of Triamcinolone Acetonid in Alopecia Areata

Protocol summary

Study aim
Comparison of therapeutic effect of different concentrations of Triamcinolone Acetoneide injection in Alopecia Areata

Design
A randomized controlled trial, parallel group, single-blind and is divided into three groups of 15 with coin hair loss in head.

Settings and conduct
Background: High prevalence of disease and its importance in causing various psychological problems and decreasing self-esteem and social function of patients, Study Area: Patients Referred to Dermatology Clinic of Sina Hospital in Tabriz, Procedure and Method of Blindness: In all specimens with more than one lesion, if there is a lesion more than 3 cm away from central lesion at site of drug injection, blind as placebo. will be. Sample size is randomly divided into three groups of 15 people. After informed consent from the patients, the drug is injected.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Alopecia areata patients with one or more patch lesions, Patients 15 years and older, Patients with full consent to participate in the study, Disease for 3 to 12 months without any signs of new hair growth at the lesion site, Exclusion Criteria:Children, Background or presence of skin diseases such as psoriasis, seborrheic dermatitis, and malignancy and infection at the site Patients with malignancy and blood dyscrasia, Pregnant and lactating women, Patients with mental retardation and physical disability, Patients who have received topical or systemic corticosteroids and topical treatments in Alopecia Areata or immunosuppressive drugs over the past month, People with autoimmune thyroid disease, type I diabetes, vitiligo, etc, A history of epilepsy (seizure).

Intervention groups
Different concentrations of Triamcenolone Acetoneide will be injected intralesional in doses of 2.5 mg per ml, 5 mg per ml and 10 mg per ml.

Main outcome variables
New Hear Growth, Number & Length of Them.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100314003566N10**
Registration date: **2020-03-04, 1398/12/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-04, 1398/12/14**
Update count: **0**

Registration date
2020-03-04, 1398/12/14

Registrant information

Name
Hamide Azimi

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 41 1540 6612

Email address
azimih@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-07, 1398/10/17

Expected recruitment end date
2020-04-20, 1399/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative Efficacy of Different Concentrations of Triamcinolone Acetonid in Alopecia Areata

Public title
Triamcinolone Acetonid in Alopecia Areata
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Alopecia areata patients with one or more patch lesions. Patients 15 years and older Patients who declare their full consent to participate in the study. The duration of the disease is 3 to 12 months and there is no sign of new hair growth at the site of the lesion.
Exclusion criteria:
Children Background or presence of skin diseases such as psoriasis, seborrheic dermatitis, and malignancy and infection at the site Patients with malignancy and blood dyscrasia Pregnant and lactating women Patients with mental retardation and physical disability Patients who have received topical or systemic corticosteroids and topical treatments in alopecia areata or immunosuppressive drugs over the past month. People with autoimmune, type I diabetes, etc. No seizure
Age
From **15 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly selected using a sealed envelope. The letters A, B and C will be used in the envelopes, and none of the study members will be aware of the contents of the envelopes.
Blinding (investigator's opinion)
Single blinded
Blinding description
The drug will be injected in all specimens at different doses and in all specimens with more than one lesion; if there is a lesion more than 3 cm away from the central lesion at which the drug is injected, The face will be blind as a placebo injection.
Placebo
Used
Assignment
Parallel
Other design features
not to use.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Golgasht Ave., Azadi St., Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2020-01-06, 1398/10/16
Ethics committee reference number
IR.TBZMED.REC.1398.1058

Health conditions studied

1

Description of health condition studied
Alopecia Areata
ICD-10 code
L63.8
ICD-10 code description
Other alopecia areata

Primary outcomes

1

Description
Number and Length of new hear at lesion site
Timepoint
Monthly
Method of measurement
Clinical Examination of Number and Length of new hear at lesion site

Secondary outcomes

1

Description
New Hear Growth Rate
Timepoint
Monthly
Method of measurement
Clinical Examination of New Hear Growth Rate on Injection Site

Intervention groups

1

Description
Intervention group 1: Intra-lesional injection of triamcinolone acetonide with a dose of 2.5 mg/ml.
Category
Treatment - Drugs

2

Description
Intervention group 2: Intra-lesional injection of triamcinolone acetonide with a dose of 5 mg/ml.
Category
Treatment - Drugs

3

Description
Intervention group 3: Intra-lesional injection of triamcinolone acetonide with a dose of 10 mg/ml.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology Clinic in Sina Hospital
Full name of responsible person
Jalal Laddin Mahdavi Roshan
Street address
Betewn Montazeri & Hafez Crossroad, Azadi Ave., Sina Hospital,Tabriz
City
Tabriz
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East Azarbaijan
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5163639888
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Email
azimi@tbzmed.ac.ir
Web page address
https://fa.irct.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr Ata Mahmoudpour
Street address
No.2, Center Department ,Golgasht St.
City
Tabriz
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East Azarbaijan
Postal code
51386631357
Phone
+98 41 3553 9161
Email
lahroudin@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
10
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Hamideh Azimi Alamdari
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Dermatology
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between Montazeri and Hafez crossroad, Azadi Street, Sina Hospital
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Person responsible for scientific inquiries

Contact

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Hamideh Azimi Alamdari

Position
Consultant

Latest degree
Specialist

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Person responsible for updating data

Contact

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Hamideh Azimi Alamdari

Position
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azimi@tbzmed.ac.ir

Web page address
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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
All data will be shared after being unidentified.

When the data will become available and for how long
At any time

To whom data/document is available
It will be free for everyone

Under which criteria data/document could be used
There are no special conditions

From where data/document is obtainable
Email:azimi@tbzmed.ac.ir , Dr Hamideh Azimi 09141168015, Dermatology Department- Sina Hospital- Azadi Street- Tabriz.

What processes are involved for a request to access data/document
The Request will be checked, then data will be sent by Email in 1 month.

Comments