

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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 Triamcencolone 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 Hair 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

##### Province

East Azarbaijan

##### Postal code

5163639888

##### Phone

+98 41 3541 2101

##### Fax

+98 41 3541 2151

##### 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

#### Province

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

##### Street address

between Montazeri and Hafez crossroad, Azadi Street, Sina Hospital

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hamideh Azimi Alamdari

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Consultant

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Specialist

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## Person responsible for updating data

### Contact

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Tabriz University of Medical Sciences

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Hamideh Azimi Alamdari

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**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**