Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the efficacy and side effects of intralesional methotrexate injection in comparison with intralesional triamcinolone acetonide in patients with alopecia areata in patients referred to Razi Hospital in 2021-2022

Protocol summary

Study aim

Efficacy and side effects of intralesional methotrexate injection in comparison with intralesional triamcinolone acetonide in patients with alopecia areata in patients referred to Razi Hospital in 2020-2021

Design

Two arm parallel group randomized double-blind clinical trial, phase 3 on 40 patients.Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct

Patients with alopecia areata referred to Razi Hospital who met the necessary criteria to enter the study were divided into two groups receiving intralesional methotrexate and intralesional triamcinolone acetonide. The study is double blind and the patient and clinical assessors are blinded.

Participants/Inclusion and exclusion criteria

The inclusion criteria for adult patients (aged 60-16 years) with patchy alopecia areata that involve less than 20% of the skin surface and the presence of areata patches on both sides of the head with a size of at least 10 square meters (both sides are patchy and relatively It should be similar and if there is aphiasis on both sides.) and they have not received any treatment for AA in the last 1 month. Exclusion criteria include children and patients under 16 years of age, pregnant and lactating women, chronic patients including patients with liver or blood disorders, patients with immunodeficiencies, infectious diseases, patients with widespread types (alopecia totalis, alopecia universalis and involvement is more than 20%) and patients who were treated for alopecia areata during the previous 1 month.

Intervention groups

Patients were randomly divided into control and intervention groups. The intervention group received intralesional methotrexate and the control group received intralesional triamcinolone acetonide.

Main outcome variables

Hair regrowth rate,change in SALT score before and after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020250N6**
Registration date: **2023-05-29, 1402/03/08**
Registration timing: **retrospective**

Last update: **2023-05-29, 1402/03/08**
Update count: **0**

Registration date

2023-05-29, 1402/03/08

Registrant information

Name

Narges Ghandi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-30, 1401/11/10

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and side effects of intralesional methotrexate injection in comparison with intralesional triamcinolone acetonide in patients with alopecia areata in patients referred to Razi Hospital in 2021-2022

Public title

Intralesional methotrexate injection in alopecia areata

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients (aged 16-60 years) Patients with alopecia areata who have less than 20% involvement of the scalp have not received any treatment for AA in the past 1 month.

Exclusion criteria:

Children and patients under 16 years, pregnant and lactating women, chronic patients including patients with liver or blood disorders, patients with immunodeficiency, infectious disease patients with diffuse types (alopecia totalis, alopecia universalis and more than 20%) and positive pull tests that are candidates for systemic treatment patients who were treated for alopecia areata during the previous month

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups Limited randomization (Random Allocation Law) Randomization unit: individual The law of random assignment is the simplest method of limited randomization. This method represents a large block for the entire sample volume, which means that the balance in the number of people assigned to each group will be achieved at the end of the study. For this purpose, the researchers first determined a total sample size, then randomly selected groups assign them to group A and the rest to group B. For example, in a study with a sample size of 200 people, 100 balls for intervention group A and 100 balls for intervention group B are placed in a lottery container and then The balls are randomly removed from the container without replacement and the created sequence is recorded.

Blinding (investigator's opinion)

Double blinded

Blinding description

A double-blind study is a study in which neither the participant nor the experimenter knows who is receiving which treatment. This method is used to prevent bias in the results. Double-blind research helps to reduce the effects of people's orientation on the research. This orientation can include the unwanted influence of the researcher on the way of collecting information or dividing people into groups. Researchers sometimes unintentionally interfere in the research process due to their feelings about the research path or personal interest in obtaining a specific result. Double-blind studies are usually conducted on humans, the factors that can bias the results of the experiment remain hidden from both the participant and the experimenter (or experimenters). In most cases, double-blind tests are performed in order to achieve a higher scientific standard.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of medical sciences

Street address

Tehran University of Medical Sciences, Office of Vice Chancellor for Research and Technology, 6th floor, Ghods Street, Keshavarz Boulevard

City

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Province

Tehran

Postal code

1417613151

Approval date

2022-02-12, 1400/11/23

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1311

Health conditions studied

1

Description of health condition studied

Alopecia Areata

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Alopecia Areata severity index

Timepoint

The beginning of the study, one month, two months, three months, six months after the start of the study.

Method of measurement

Viewing Dermoscopy criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: a vial of methotrexate containing 25 mg/ml is used. After septic procedures, methotrexate is injected intradermally in the lesion itself and one centimeter around it with an injection volume of 0.02 ml per site. A maximum of 0.1-0.2 ml (2.5-5 mg) is injected per session using a 0.5 inch length. A 30 mm needle connected to an insulin syringe will be used.

Category

Treatment - Drugs

2

Description

Control group: The amount of intralesional steroids used is 40 mg/ml. One-fifth diluted triamcinolone acetonide (8 mg/ml) is injected intradermally in the lesion itself and one centimeter around it with an injection volume of 0.05-0.1 ml per site. A maximum of 2 ml (20 mg) is injected per session using a length of 0.5 inches. A 30 mm needle connected to an insulin syringe will be used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Diphencyprone Clinic- Razi Dermatology Hospital

Full name of responsible person

Doctor Narges Ghandi

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Razi Blind Alley, Vahdate-Islami Square, Vahdate-Islami Street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of Research and Technology,Tehran University of Medical Sciences and Health Services

Full name of responsible person

Dr.Akbar fotuhi

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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

Vice chancellor of Research and Technology,Tehran University of Medical Sciences and Health Services

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Narges Ghandi

Position
Professor
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available