Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative evaluation of the response rate based on tricoscopic criteria in patients with severe alopecia areata treated with diphencyprone with or without intralesional platelet rich plasma

Protocol summary

Study aim

Comparative evaluation of response to treatment based on trichoscopic criteria in patients with severe alopecia areata treated with diphen cypron with and without intra-lesional platelet rich plasma injection

Design

A clinical trial with 20 sample size of patient with severe alopecia areata. Every patient is their own control single groups, double blinded and randomized (Random block)

Settings and conduct

Patients are selected from referrals to Diphen Ciprone Clinic at Department of Dermatology, Razi Hospital. The test was performed with 2% diphen cypron solution and continues based on routine protocols for whole scalp. after reaching the appropriate concentration, PRP injection sessions begin on one side of the scalp. Randomized block method was used to randomize treatments to the head sides (left and right). Inject 3 sessions at one month interval. The study is double-blinded (Participant,Outcome assessor and data analyser are blinded and Care provider (Investigator) are aware)

Participants/Inclusion and exclusion criteria

Inclusion 1.Patients with severe alopecia areata (> 50% scalp and less than 100%) 2. Positive response to test with 2% Diphen Ciprone solution exclusion 1. alopecia totalis/universalis 2. Receiving systemic treatment in the past 6 months 3. Children under 18 years 4. Pregnant and lactating women 5. Immunosuppressants 6. People with platelet dysfunction 7. Taking intralesional steroid over the last month 8. Fever, systemic and topical infection at the injection site

Intervention groups

All patients receive the intervention, which is the injection of platelet-rich plasma(PRP). Every person is their own control. the whole scalp takes Diphen Ciprone and only one side (right or left) takes PRP.

Main outcome variables

Patients with severe alopecia areata respond more significantly to treatment with PRP and diphenyl cyprone together in comparison with diphenyl cyprone alone

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200130046311N1**
Registration date: **2021-04-13, 1400/01/24**
Registration timing: **retrospective**

Last update: **2021-04-13, 1400/01/24**
Update count: **0**

Registration date

2021-04-13, 1400/01/24

Registrant information

Name

azadeh rezayat

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-29, 1398/12/10

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative evaluation of the response rate based on tricoscopic criteria in patients with severe alopecia areata treated with diphencyprone with or without intralesional platelet rich plasma

Public title
Comparison of the effect of DiphenCiprone alone and DiphenCiprone with intralesional injection of platelet-rich plasma in alopecia areata
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
A patient with alopecia areata whose definitive diagnosis was made on clinical or histological basis and their involvement was severe (> 50% scalp area and less than 100%). Positive response to test with 2% Diphen Ciprone solution
Exclusion criteria:
Patients with alopecia totalis or universalis Receive any systemic treatment during the last 6 months Children under 18 years Pregnant and lactating women Immunosuppressed patient patient with platelet dysfunction patient with a history of injecting steroids on the site over the past month Fever, systemic infection and local infection at the injection site
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomized block method was used to randomize treatments to the two different head area(left and right). Blocks in the size of 2 and 4 were used to generate random blocks
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients participating in the study were unaware of which side of the scalp received PRP and which side the placebo. The care provider , who is also the investigator, is aware of this. People who analyze photographic images to determine SALT and dermoscopic images are unaware. The statistical consultant for data analysis is also unaware.
Placebo
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
Building No. 1 - Enghelab Ave. - Qods Street - Porsina Street - North Door of the University Tehran, Iran
City
tehran
Province
Tehran
Postal code
1417653761
Approval date
2019-09-20, 1398/06/29
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.505

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
severity alopecia tool score (SALT score)
Timepoint
Trichoscopic evaluation at baseline, 3 months later, 6 months later
Method of measurement
Trichoscope

Secondary outcomes

1

Description

SALT score evaluation

Timepoint

Evaluation at baseline, 3 months later, 6 months later

Method of measurement

visual evaluation

Intervention groups

1

Description

Intervention group: taking Diphen Ciprone and platelet-rich plasma together. All patients participating in the study received diphen cyprone and PRP simultaneously on one side of their head (right or left randomized). Patients who respond positively to 2% diphen cyprone solution enter the next stages of treatment, starting with 0.0001% solution. After this, the patient goes to the Diphen Cypron clinic every one to two weeks and based on the patient's symptoms and the discretion of the physician, the treatment is continued with a gradual increase in the drug concentration. PRP injection is started as soon as the appropriate concentration of diphen cyprone is reached for each patient (causing mild, tolerable itching, scaling, and erythema). PRP injection is done with a one-month interval of 3 sessions.

Category

Treatment - Other

2

Description

Control group: Each person is his own control. This means that the opposite side of the head (right or left) is treated with topically Diphen cyprone and placebo injection. Its frequency and dose are completely in accordance with the intervention group

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi dermatology hospital

Full name of responsible person

Azadeh Rezayat

Street address

Razi Dermatology Specialty Hospital, Razi Stand, Islamic Unity Square, Islamic Unity St., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Deputy of research and technology,Central University Organization,Sixth Floor, Ghods Ave., Keshavarz Blvd.

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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

Tehran University of Medical Sciences

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

Azadeh Rezayat

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Latest degree
Specialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

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

Data Dictionary
Not applicable

Title and more details about the data/document
All data can be shared

When the data will become available and for how long
after the end of study

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
For research and study

From where data/document is obtainable
first responsible of the study

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

Comments