

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation and comparison of the efficacy and safety of two regimens of diphencyclopropenone (applying different concentrations to identify the effective concentration vs. traditional method) in the treatment of alopecia areata in patients referred to Razi Hospital, 1398-1399.

Protocol summary

Study aim

comparision of the rate of terminal hair regrowth, time duration to respond to treatment, side effects and patient's satisfaction with diphencyprone (DPCP) with two different regimens, in two separate groups of patients with alopecia areata(AA), based on Severity of Alopecia Tool (SALT) score

Design

clinical trial phase 3, 60 patients, two parallel block randomized groups of 30 patients, followed for 6 months

Settings and conduct

After providing information and obtaining informed consent, 60 patients referring to Razi Hospital DPCP clinic are recruited into the study and randomized between two groups. Regular follow ups will be performed by investigators.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients more than 18 years old with AA ; hair loss grater than 50% ; possibility fo regular visit.exclusion criteria: pregnancy or lactation; systemic immunosuppressive therapy during recent 3 months; hematologic dycrasia ; no response to diphencyprone test ; having androgenitic alopecia ; persistent totalis or universalis areata alopecia from infancy

Intervention groups

Two similar groups with AA ,patients in one group receive DPCP with old regimen ; patients in another group receive DPCP with new redimen ; groups are followed for 6 months in a parallel form

Main outcome variables

Hair regrowth rate; change in SALT score before and after treatment; time to response to treatment; side effects of treatment; patients satisfaction with treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020250N5**

Registration date: **2019-11-24, 1398/09/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-24, 1398/09/03**

Update count: **0**

Registration date

2019-11-24, 1398/09/03

Registrant information

Name

Narges Ghandi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5561 8989

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nghandi@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the efficacy and safety of two regimens of diphencyclopropenone (applying different concentrations to identify the effective concentration vs. traditional method) in the treatment of alopecia areata in patients referred to Razi Hospital, 1398-1399.

Public title

The comparison of two regimens of diphencyprone in alopecia areata patients.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with alopecia areata Possibility of regular visit for the patient Hair loss more than 50 % The age of the patient greater than 18 years old

Exclusion criteria:

Pregnancy and lactation Persistent totalis or universalis areata alopecia from infancy Prominent androgenetic alopecia No response to diphencyprone test Patients with hematologic dysplasia receiving systemic immunosuppressive therapy during recent 3 months

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

Blinding (investigator's opinion)

Not blinded

Blinding description**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

Fourth floor, No 23, before Poursina Street, 16 Azar Street, Keshavarz Boulevard

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Province

Tehran

Postal code

1417653761

Approval date

2019-08-24, 1398/06/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.432

Health conditions studied**1****Description of health condition studied**

alopecia areata

ICD-10 code

L63

ICD-10 code description

Alopecia areata

Primary outcomes**1****Description**

terminal hair regrowth rate with topical diphencyprone with old regimen in comparison to new regimen in patients with alopecia areata, based of SALT score

Timepoint

before intervention and 3 and 6 months after intervention

Method of measurement

Severity of Alopecia Tool Score

Secondary outcomes**1****Description**

rate of change in Severity of Alopecia Tool score than the base value, after intervention and at the end of course of treatment

Timepoint

3 and 6 months after treatment

Method of measurement

Severity of Alopecia Tool score

Intervention groups**1****Description**

Intervention group1: 30 patients with alopecia areata who are receiving topical diphencyprone with new regimen.

Category

Treatment - Drugs

2

Description

Intervention group 2: 30 patients with alopecia areata who are receiving topical diphencyprone with old regimen

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

Tehran University of Medical Sciences

Full name of responsible person

Doctor Seyyed Ahmad Rezayi

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sixth floor, Vice Chancellor Of Research And Technology, central organization of Tehran University Of Medical Sciences, at the corner of Qods Street, Keshavarz Boulevard

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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

Doctor Alaa Al Bazzal

Position

Dermatology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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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