

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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

comparison 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 greater 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 androgenic 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

##### Email address

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

**City**

Tehran

**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

**Street address**

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

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razihospital@sina.tums.ac.ir

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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

**Street address**

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

### Contact

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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