Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ctiteria: 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

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 then 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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http://razihos.tums.ac.ir/

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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rmo@tums.ac.ir
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
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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