Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the efficacy and side effects of topical diphencyprone with or without topical anthralin in patients with moderate to severe alopecia areata referring to Razi Hospital Diphencyprone Clinic, 2018- 2019.

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) alone and DPCP with anthralin, in two separate groups of patients with moderate to severe alopecia areata(AA), based on Severity of Alopecia Tool (SALT) score

Design

clinical trial phase 3, 40 patients, two parallel block randomized groups of 20 patients, followed for 6 months

Settings and conduct

After providing information and obtaining informed consent, 40 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 18 to 65 years old with moderate to severe AA exclusion criteria: pregnancy or lactation; systemic immunosuppressive therapy during recent 3 months; severe systemic disease (eg.hepatic or renal failure); immunocompromised patients; past history of severe reactions or intolerance to DPCP or anthralin; inability to follow regular visits or cooperation with investigators; participation in another clinical trial in recent 4 weeks; recent active severe progressive hair loss requiring systemic immunosuppressive therapy

Intervention groups

Two similar groups with moderate to severe AA ,patients in one group receive only DPCP; patients in another group receive DPCP and anthralin simultaneously; 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: **IRCT20141209020250N4**
Registration date: **2018-06-30, 1397/04/09**
Registration timing: **prospective**

Last update: **2018-06-30, 1397/04/09**
Update count: **0**

Registration date

2018-06-30, 1397/04/09

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

2018-07-07, 1397/04/16

Expected recruitment end date

2018-08-07, 1397/05/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the efficacy and side effects of topical diphencyprone with or without topical anthralin in patients with moderate to severe alopecia areata referring to Razi Hospital Diphencyprone Clinic, 2018-2019.

Public title
Diphencyprone and anthralin in alopecia areata
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
moderate to severe alopecia areata
Exclusion criteria:
pregnancy or lactation receiving systemic immunosuppressive therapy during recent 3 months severe systemic disease (eg. hepatic or renal failure) immunosuppression past history of severe reaction or intolerance to diphencyprone or anthralin inability to follow regular visits or cooperation with investigators participation in another clinical trial in recent 4 weeks recent active sever progressive hair loss requiring systemic immunosuppressive therapy
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
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
2018-01-31, 1396/11/11
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.3821

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 in comparison to the combination of topical diphencyprone with topical anthralin in patients with moderate to severe alopecia areata, based of SALT score
Timepoint
before intervention and 3 and 6 months after intervention
Method of measurement
Severity of Alopecia Tool Score

2

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

3

Description
comparison of response time to treatment with topical diphencyprone exclusively or combination of topical diphencyprone and anthralin
Timepoint
3 and 6 months after intervention
Method of measurement
time duration (month)

Secondary outcomes

1

Description
evaluation of patients' satisfaction with topical diphencyprone with and without topical anthralin at the end of the survey, using Dermatology Life Quality Index questionnaire
Timepoint
6 months after treatment
Method of measurement
Dermatology Life Quality Index questionnaire

2

Description
investigating side effects of treatment (eg. dermatitis , lymphadenopathy , folliculitis , urticaria and etc.)
Timepoint
3 and 6 months after treatment
Method of measurement
patient examination and history

Intervention groups

1

Description
Intervention group 1: 20 patients with moderate to severe alopecia areata who are receiving just topical diphencyprone
Category
Treatment - Drugs

2

Description
Intervention group 2: 20 patients with moderate to severe alopecia areata who are receiving both topical diphencyprone and topical anthralin
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
City
Tehran
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Postal code
1199663911
Phone
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Email
razihospital@sina.tums.ac.ir
Web page address
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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Phone
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Email
rmo@tums.ac.ir
Web page address
http://rmo.tums.ac.ir/
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
Doctor Romina Daneshmand
Position
Dermatology Resident
Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Razi Dermatology Hospital, Razi blind Alley, Vahdate-Islami Square, Vahdate-Islami Street, Tehran

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Position

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Latest degree

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Person responsible for updating data

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Doctor Romina Daneshmand

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Phone

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Email

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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