

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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

comparison 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 criteria: 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 severe 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

Province

Tehran

Postal code

1199663911

Phone

+98 21 5560 9951

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

City

Tehran

Province

Tehran

Postal code

1417653761

Phone

+98 21 8163 3619

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

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5560 9951

Email

r-daneshmand@razi.tums.ac.ir

Person responsible for scientific 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

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5560 9951

Email

r-daneshmand@razi.tums.ac.ir

Person responsible for updating data

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

City

Tehran

Province

Tehran

Postal code

1199663911

Phone

+98 21 5560 9951

Email

r-daneshmand@razi.tums.ac.ir

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