

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluating the safety and efficiency of the combined use of mask and hair spray with the iDR brand, a product of Vera Rahesh Pharmed Company in repairing and improving the appearance of damaged hair compared to placebo.

Protocol summary

Study aim

Evaluating the safety and efficiency of the combined use of mask and hair spray with the iDR brand in repairing and improving the appearance of damaged hair compared to placebo.

Design

The study is a phase 2-3 clinical trial, cross over, randomized and double-blind comparison with placebo. Randomization is done simply using block randomization.

Settings and conduct

The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 14 volunteers will be selected and enrolled in the study after signing consent form. Volunteers are taught to use of iDR brand hair spray and mask after bathing for two weeks or a placebo. Blinding the participants will be such that both products will be packed in the same containers, that are distinguished from each other only by code number on the packaging. In order to blind the outcome assessor, the randomization list will be provided to a third person and the allocation of formulations to each of the participants will be done after receiving the random code. Before intervention, 30 minutes after using and 2 weeks after not using changing in Hair shining will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: female aged 18-55 years, Good general health, Voluntary participation and sign the written informed consent. Exclusion criteria: Pregnancy and breastfeeding.

Intervention groups

Intervention group: Using iDR brand hair spray and mask after bathing for two weeks, at least 4 times. Depending on length and volume of the hair, one to three milliliters of the product should be used on the hair. After 5 minutes, use two puffs of iDR hair mask on the hair and

avoid washing it. Control group: Using spray with the same packaging as the original product containing normal saline and mask without active ingredients after bathing for two weeks, at least 4 times

Main outcome variables

Hair shine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210130050179N8**

Registration date: **2023-12-27, 1402/10/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-27, 1402/10/06**

Update count: **0**

Registration date

2023-12-27, 1402/10/06

Registrant information

Name

Taraneh Yazdanparast

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8897 2220

Email address

drtaraneh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-27, 1402/10/06
Expected recruitment end date
2024-08-27, 1403/06/06
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the safety and efficiency of the combined use of mask and hair spray with the iDR brand, a product of Vera Rahesh Pharmed Company in repairing and improving the appearance of damaged hair compared to placebo.

Public title
Evaluating the safety and efficiency of the combined use of mask and hair spray with the iDR brand in repairing and improving the appearance of damaged hair

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
female aged 18-55 years. Good general health People with damaged hair naturally or after using hair color, including tangles, frizz, frizz, dullness. Voluntary participation and sign the written informed consent.
Exclusion criteria:
People with known allergies to mask or spray ingredients Active acute or chronic scalp disease such as psoriasis, lichen planus, etc. Having any type of malignancy Scalp surgeries Pregnancy and breastfeeding Change in shampoo used or supplements taken such as zinc and vitamin C during the study. Using 2 in 1 shampoo containing softener, hair ointment, hair gel or tuft during the study

Age
From **18 years** old to **55 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **14**

Randomization (investigator's opinion)
Randomized

Randomization description
14 people are assigned to one of AB, BA sequences using block randomization.

Blinding (investigator's opinion)
Double blinded

Blinding description
The physician and expert evaluating the results and the participants are unaware of the type of products offered in each cycle. Blinding the participants will be such that both products will be packed in the same containers, that

are distinguished from each other only by code number on the packaging. In order to blind the outcome assessor, the randomization list will be provided to a third person and the allocation of formulations to each of the participants will be done after receiving the random code.

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of The Institute of Pharmaceutical Sciences of Tehran University of Medical Science
Street address
Unit 1-219, 2nd floor, The Institute of Pharmaceutical Sciences, Faculty of Pharmacy, 16 Azar Avenue
City
Tehran
Province
Tehran
Postal code
1417613151
Approval date
2023-12-12, 1402/09/21
Ethics committee reference number
IR.TUMS.TIPS.REC.1402.127

Health conditions studied

1

Description of health condition studied
hair damage
ICD-10 code
L67
ICD-10 code description
Hair color and hair shaft abnormalities

Primary outcomes

1

Description
Hair shine
Timepoint
Before intervention, 30 minutes and two weeks after use
Method of measurement
By Glossymeter probe from the device Multi Probe Adapter (MPA)

Secondary outcomes

1

Description

Number of people in improved or better condition

Timepoint

Before intervention, 30 minutes and two weeks after use

Method of measurement

Based on GAIS criteria: 0 = worse than baseline pretreatment appearance, 1 = no change, 2 = improved, 3 = much improved, 4 = excellent improvement

2

Description

The level of satisfaction of consumers in general and also separately for each of the parameters of hair softness, hair manageability, easy to comb and maintaining shine.

Timepoint

Before intervention, 30 minutes and two weeks after use

Method of measurement

based on not at all satisfied (-2), not satisfied (-1), not having a particular opinion (0), almost satisfied (1), very satisfied (2)

Intervention groups

1

Description

Intervention group: Using iDR brand hair spray and mask after bathing for two weeks, at least 4 times. Depending on length and volume of the hair, one to three milliliters of the product should be used on the hair. After 5 minutes, use two puffs of iDR hair mask on the hair and avoid washing it.

Category

Treatment - Drugs

2

Description

Control group: Using spray with the same packaging as the original product containing normal saline after bathing for two weeks, at least 4 times. Depending on length and volume of the hair, one to three milliliters of hair mask with mask base composition, without active ingredients on the hair and avoid washing it.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for research and training in skin diseases and leprosy

Full name of responsible person

Aniseh Samadi

Street address

No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.

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1416613675

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dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vera Rahesh Pharmed Pharmaceutical Company

Full name of responsible person

Alireza Mohamadrezai

Street address

Kavush Building, Danesh 2, Innovation 4, Pardis Technology Park, 16th Km Jajrud

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1654120914

Phone

+98 935 245 9362

Email

a.rezaei@virarahesh.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vera Rahesh Pharmed Pharmaceutical Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Taraneh Yazdanparast

Position

Research Physician

Latest degree

Ph.D.

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Position

Professor of dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Maryam Ahmadi

Position

Research Expert

Latest degree

Master

Other areas of specialty/work

Dermatology

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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

Not applicable

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

Not applicable

Data Dictionary

Not applicable