Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the effectiveness of biotin and dexpanthenol ampoules produced by Pars Behruzan Jam company in comparison with reference drugs (produced by Bayer German company) in reducing diffuse and scattered hair loss

Protocol summary

Study aim
Evaluation of the effectiveness of biotin and dexpanthenol ampoules produced by Pars Behruzan Jam company in comparison with reference drugs (produced by Bayer German company) in reducing diffuse and scattered hair loss

Design
parallel group, phase 2, parallel treatment-control clinical study. sample size is 50. The study is randomized and one-way blind. An online site (https://www.sealedenvelope.com) and random block method will be used to randomization.

Settings and conduct
The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy. 50 volunteers will be selected and enrolled in the study after signing consent form. Volunteers will be enrolled to one of intervention or control groups according to the randomization list; biotin and dexpanthenol ampoules produced by Pars Behruzan Jam company in comparison with produced by Bayer German company

Participants/Inclusion and exclusion criteria
Inclusion criteria: Male or female aged 18-55 years diffuse and scattered hair loss General health Voluntary participation and signing written informed consent Exclusion criteria: Pregnancy or breastfeeding Chronic active scalp disease other than hair loss Using any prescribed drug or OTC for hair loss within the past 3 months People with allergies to drug ingredients

Intervention groups
Intervention group: Injection of 6 ampoules of Dexpanthenol produced by Pars Behruzan Jam Company, as a muscle injection, within 6 weeks+Injection of 6 ampoules of Biotin , produced by Pars Behruzan Jam Company, as a muscle injection, within 6 weeks Control group: Injection of 6 ampoules of Dexpanthenol, produced by Bayer Company, as a muscle injection, within 6 weeks+ Injection of 6 ampoules of Biotin, produced by Bayer Company, as a muscle injection, within 6 weeks

Main outcome variables
Hair lost Changes, based on Global photographic review

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190210042676N10**
Registration date: **2020-07-19, 1399/04/29**
Registration timing: **prospective**

Last update: **2020-07-19, 1399/04/29**
Update count: **0**

Registration date
2020-07-19, 1399/04/29

Registrant information

Name
Aniseh Samadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8897 2220

Email address
a_samadi@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of biotin and dexpanthenol ampoules produced by Pars Behruzan Jam company in comparison with reference drugs (produced by Bayer German company) in reducing diffuse and scattered hair loss

Public title

Evaluation of the effectiveness of biotin and dexpanthenol ampoules produced by Pars Behruzan Jam company in reducing hair loss

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male or female aged 18-55 years diffuse and scattered hair loss General health Voluntary participation and signing written informed consent

Exclusion criteria:

Pregnancy or breastfeeding Chronic active scalp disease other than hair loss Using any prescribed drug or OTC for hair loss within the past 3 months People with allergies to drug ingredients Any severe weight loss or strict diet therapy during the study

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

An online site (https://www.sealedenvelope.com) will be used to generate a randomized list of study groups. According to the random block method and considering the four blocks, 12 blocks will be produced for 50 patients.

Blinding (investigator's opinion)

Single blinded

Blinding description

The clinicians who performed the clinical assessments and objective device analysis are completely blinded to the treatment type. participants will receive the treatment according to the randomization list by an independent assistant.

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

Research and Technology Dept, 6th floor, Central Organization of the University, Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-05-07, 1399/02/18

Ethics committee reference number

IR.TUMS.VCR.REC.1399.346

Health conditions studied

1

Description of health condition studied

hair loss

ICD-10 code

L65.9

ICD-10 code description

Nonscarring hair loss, unspecified

Primary outcomes

1

Description

Hair lost Changes, based on Global photographic review

Timepoint

Before intervention, 1 and 8 weeks after last injection

Method of measurement

One independent dermatologist will perform clinical assessments in a blinded fashion by scoring every photograph according to the Global photographic review scale .

Secondary outcomes

1

Description
Hair count changes
Timepoint
Before intervention, 1 and 8 weeks after last injection
Method of measurement
Dermatoscopy By Fotofinder

2

Description
Changes in percentage of anagen to telogen
Timepoint
Before intervention, 1 and 8 weeks after last injection
Method of measurement
Dermatoscopy By Fotofinder

Intervention groups

1

Description
Intervention group: Injection of 6 ampoules of Dexpanthenol 250 mg / 2 ml, produced by Pars Behruzan Jam Company, as a muscle injection, within 6 weeks+Injection of 6 ampoules of Biotin 5 mg /ml, produced by Pars Behruzan Jam Company, as a muscle injection, within 6 weeks
Category
Treatment - Drugs

2

Description
Control group: Injection of 6 ampoules of Dexpanthenol 250 mg / 2 ml, produced by Bayer Company, as a muscle injection, within 6 weeks+ Injection of 6 ampoules of Biotin 5 mg /ml, produced by Bayer Company, as a muscle injection, within 6 weeks
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.
City
Tehran
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Tehran
Postal code
1416613675
Phone
+98 21 8897 0658
Email
dermalab@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pars Behruzan Jam Company
Full name of responsible person
Jamshid Nategholeslam
Street address
Unit 3, No. 3, West Fatemi St.
City
Tehran
Province
Tehran
Postal code
1411816444
Phone
+98 21 6642 3315
Email
ddk.pharma69@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pars Behruzan Jam 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
Aniseh Samadi
Position
Manger of clinical study unit
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
No. 415, Shahid Naderi (Soheil) St., Taleqani Ave.
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aniseh_samadi@yahoo.com

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
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Tehran University of Medical Sciences
Full name of responsible person
Maryam Ahmadi
Position
Research Expert
Latest degree
Master
Other areas of specialty/work
Clinical Research
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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