

# 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 dexpantenol 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 dexpantenol 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

##### Province

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

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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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firozali@sina.tums.ac.ir

## 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**  
Clinical Research  
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ahmadi.maryam648@gmail.com

## 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