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
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
### Description

**Hair count changes**

**Timepoint**

Before intervention, 1 and 8 weeks after last injection

**Method of measurement**

Dermatoscopy By Fotofinder

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### Description

Changes in percentage of anagen to telogen

**Timepoint**

Before intervention, 1 and 8 weeks after last injection

**Method of measurement**

Dermatoscopy By Fotofinder

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### 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

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**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

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### 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

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### 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.

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**Province**

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**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

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### 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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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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Maryam Ahmadi  
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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