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 Dexpantenol produced by Pars Behruzan Jam 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
Control group: Injection of 6 ampoules of Dexpantenol, 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
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 Dexamethasone 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**
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**Province**
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**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**
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**Province**
Tehran
**Postal code**
1411816444
**Phone**
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**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**
Manager 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
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Professor of 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
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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