Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of safety and the effectiveness of Bioba (Prime) anti-hair loss line (serum and shampoo) in reducing diffuse and scattered hair loss and Improving hair volume and density

Protocol summary

Study aim
Evaluation of safety and the effectiveness of Bioba (Prime) anti-hair loss line (serum and shampoo) in reducing diffuse and scattered hair loss and Improving hair volume and density

Design
Single group, phase 2, before -after clinical study. sample size is 19. The study is not randomized.

Settings and conduct
The study will be performed in Center for the Study and Research of Diseases of the Skin and Leprosy, 19 volunteers with reducing diffuse and scattered hair loss will be selected and enrolled in the study after signing consent form. Volunteers will be taught to use Bioba (Prime) anti-hair loss serum and shampoo produced by Akhavi laboratory for 12 weeks once in a day. Before intervention , 6 and 12 weeks after using changing in hair count and volume will be measured. This study is not blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Male or female aged 18-55 years, Diffuse and scattered hair loss (Count at least 300 hairs in a combing test over three days), General health, Voluntary participation and signing written informed consent Exclusion criteria: Chronic active scalp disease other than hair loss, Using any prescribed drug or OTC for hair loss within the past 3 months, Any severe weight loss or strict diet therapy during the study, Pregnancy or breastfeeding

Intervention groups
Topical use of Bioba (Prime) anti-hair loss serum produced by Akhavi laboratory (Contains Concentrated Silatol, Decarboxy carnosine, B vitamins and baobab seed oil) Spray 9 times once a day, for 12 weeks and topical use of Bioba(Prime) anti-hair loss shampoo produced by Akhavi laboratory (Contains Extracts of Arnica, Baba Adam, Chamomile, Garlic, Papital, B vitamins,etc..) for 12 weeks.

Main outcome variables
Hair count changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190210042676N16**
Registration date: **2021-12-11, 1400/09/20**
Registration timing: **prospective**

Last update: **2021-12-11, 1400/09/20**
Update count: **0**

Registration date
2021-12-11, 1400/09/20

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
2021-12-22, 1400/10/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of safety and the effectiveness of Bioba (Prime) anti-hair loss line (serum and shampoo) in reducing diffuse and scattered hair loss and Improving hair volume and density

Public title
Evaluation of safety and the effectiveness of Bioba (Prime) anti-hair loss line (serum and shampoo)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male or female aged 18-55 years Diffuse and scattered hair loss (Count at least 300 hairs in a combing test over three days) General health Voluntary participation and signing written informed consent
Exclusion criteria:
Chronic active scalp disease other than hair loss Using any prescribed drug or OTC for hair loss within the past 3 months Any severe weight loss or strict diet therapy during the study Pregnancy or breastfeeding
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **19**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee in research of medical school-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
2021-11-28, 1400/09/07
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1400.969

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 count changes
Timepoint
Before intervention, 6 and 12 weeks after the start of use
Method of measurement
Trichoscopy By Fotofinder

Secondary outcomes

1

Description
Hair lost Changes, based on Global photographic review
Timepoint
Before intervention, 6 and 12 weeks after the start of use
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 .

2

Description
Changes in percentage of anagen to telogen
Timepoint
Before intervention, 6 and 12 weeks the start of use
Method of measurement
Trichoscopy By Fotofinder

Intervention groups

1

Description
Intervention group: Topical use of Bioba(Prime) anti-hair loss serum produced by Akhavi laboratory (Contains Concentrated Silatol, Decarboxy carnosine, B vitamins and baobab seed oil) Spray 9 times once a day, for 12 weeks and topical use of Bioba(Prime) anti-hair loss shampoo produced by Akhavi laboratory (Contains Extracts of Arnica, Baba Adam, Chamomile, Garlic, Papital, B vitamins,etc..) for 12 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) Street, Taleqani Avenue

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
Akhavi laboratory

Full name of responsible person
Farid Akhavi

Street address
Unit 8, No.17, Tavanir Street, Valiasr Street

City
Tehran

Province
Tehran

Postal code
1434875419

Phone
+98 21 8879 8126

Email
info@akhavilab.com

Grant name

Grant code / Reference number

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

Title of funding source
Akhavi laboratory

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
Ph.D.

Other areas of specialty/work
Skin Biometrics

Street address
No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue.

City
Tehran

Province
Tehran

Postal code
1416613675

Phone
+98 21 8896 0880

Email
aniseh_samadi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mansour Nassiri Kashani

Position
Professor of dermatology

Latest degree
Specialist

Other areas of specialty/work
Dermatology

Street address
No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue

City
Tehran
Province
Tehran
Postal code
1416613675
Phone
+98 21 8897 7921
Email
mnassirik@gmail.com

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
Street address
No. 415, Shahid Naderi (Soheil) Street, Taleqani Avenue
City
Tehran
Province
Tehran
Postal code
1416613675
Phone
+98 21 8897 0658
Email
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