

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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

AgeFrom **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

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Province

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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

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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

Manager of clinical study unit

Latest degree

Ph.D.

Other areas of specialty/work

Skin Biometrics

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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

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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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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