Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the effect of nanostructured lipid carriers containing latanoprost to control androgenic alopecia

Protocol summary

Study aim
The effect of latanoprost-containing lipid nanocarriers on androgenic alopecia
Design
Clinical trial with control group, not blinded, with parallel groups, non-randomized, phase 3, and 16 patients
Settings and conduct
In order to evaluate the effectiveness of lipid nanoparticles containing latanoprost in compare with it's solution, a study will be performed on 16 male volunteers aged 25-50 years with manifestations of androgenic hair loss. All volunteers will take both formulations of the drug at home once every 3 days. And their photography will be done and compared in a beauty clinic under the supervision of a dermatologist.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Male, age between 23 to 50 years, with androgenic alopecia Exclusion criteria: History of skin cancer, manifestations of skin disease in the desired area, history of hair transplantation
Intervention groups
Evaluation of the effect of lipid nanocarriers containing latanoprost in volunteers with androgenic alopecia on the right side of the head and a solution containing latanoprost on the left side of the head
Main outcome variables
Hair loss; Number and thickness of hair strands

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20211209053339N1**
Registration date: **2022-01-15, 1400/10/25**
Registration timing: **prospective**

Last update: **2022-01-15, 1400/10/25**
Update count: **0**
Registration date
2022-01-15, 1400/10/25

Registrant information
Name
Shadi Mahramfar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 41 3478 5226
Email address
shadi1995mahramfar@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-01-30, 1400/11/10
Expected recruitment end date
2022-03-01, 1400/12/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of nanostructured lipid carriers containing latanoprost to control androgenic alopecia

Public title
The effect of nanostructures of Latanoprost on male pattern hair loss
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Male gender Age between 23 to 50 years manifestations

of androgenic hair loss

Exclusion criteria:

History of skin cancer History of physical therapy on the scalp during the last 6 months Manifestations of skin disease in the desired area History of hair transplantation

Age

From **23 years** old to **50 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **16**

More than 1 sample in each individual

Number of samples in each individual: **2**

One sample contains latanoprost solution and the other sample contains latanoprost nanoparticles.

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Medical Education Research and Development Complex (formerly Pashmineh), Pharmaceutical Nanotechnology Research Center., Opposite to Shahid Madani Hospital.,University St.

City

Tabriz

Province

East Azarbaijan

Postal code

5165665811

Approval date

2021-04-26, 1400/02/06

Ethics committee reference number

IR.TBZMED.REC.1400.082

Health conditions studied

1

Description of health condition studied

Androgenic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

Hair diameter

Timepoint

Before starting treatment and also at weeks 4, 8, 12, 16, 20 and 24

Method of measurement

Trichoscope

2

Description

Hair color

Timepoint

Before starting treatment and also at weeks 4, 8, 12, 16, 20 and 24

Method of measurement

Trichoscope

3

Description

hair density

Timepoint

Before starting treatment and also at weeks 4, 8, 12, 16, 20 and 24

Method of measurement

Trichoscope

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Evaluation of the effect of lipid nanostructures containing latanoprost in the form of lotion on androgenic hair loss in male volunteers who will take the drug every 3 days for 6 months in amount of 0.25 cc with a 0.2% concentration on the right side of their head.

Category

Treatment - Drugs

2

Description

Evaluation of the effect of latanoprost solution on

androgenic hair loss in comparison with its nanolipid form in male volunteers who take the drug every 3 days for six months in amount of 0.25 cc with a concentration of 0.02% on the left side of the head.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Sciences

Full name of responsible person
Dr.Hamed Hamishehkar

Street address
Medical Education Research and Development Complex (formerly Pashmineh), Pharmaceutical Nanotechnology Research Center., Opposite to Shahid Madani Hospital.,University St.

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Phone
+98 41 3335 5389

Email
Hamishehkar.hamed@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr.Hamed Hamishehkar

Street address
Medical Education Research and Development Complex (formerly Pashmineh), Pharmaceutical Nanotechnology Research Center., Opposite to Shahid Madani Hospital.,University St.

City
Tabriz

Province
East Azarbaijan

Postal code
5165665811

Phone
+98 41 3335 5389

Email
Hamishehkar.hamed@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Tabriz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Shadi Mahramfar

Position
pharmacy student

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

Street address
Medical Education Research and Development Complex (formerly Pashmineh), Pharmaceutical Nanotechnology Research Center., Opposite to Shahid Madani Hospital.,University St.

City
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Province
East Azarbaijan

Postal code
5165665811

Phone
+98 41 3335 5389

Email
Shadi1995mahramfar@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Dr.Hamed Hamishehkar

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Hamishehkar.hamed@gmail.com

Person responsible for updating data

Contact

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Tabriz University of Medical Sciences

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Shadi Mahramfar

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pharmacy student

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5165665811

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+98 41 3335 5389

Email

Hamishehkar.hamed@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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments