Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

A comparative study of the therapeutic effect of topical finasteride with oral finasteride in patients with androgenetic alopecia .

Protocol summary

Study aim

Determination and comparison of the therapeutic effect of topical finasteride with oral finasteride in patients with androgenetic alopecia.

Design

The study is a randomized, controlled, blinded investigator, phase 3 trial parallel (assignment of two groups). restricted randomization method, the permuted block randomization type will be used, and a random sequence will be created using the random allocation software. Replacement blocks of 4 are assigned to two treatments (groups A, b). At least 14 people were considered for each group.

Settings and conduct

Patients are randomly selected from patients who refer to the dermatology clinic of Shahid Faqihi in Shiraz and receive drug treatment for 6 months and are examined after 3 months and at the end of 6 months. The collection tool in this study is a checklist that the results of the treatment evaluation will be recorded at the beginning of the study, at the end of the 3rd and 6th month. The assessment of the process of improving hair growth from the point of view of the patient and the doctor based on clinical judgment in terms of hair density (weak and medium and good and excellent) will be done

Participants/Inclusion and exclusion criteria

inclusion: Having androgenic alopecia grade 2 to 5 based on the Norwood Hamilton classification in men؛ age above 18 years, having androgenic alopecia grade 2 to3 according to ludwig grading in women؛ menopausal women or women over18 years of age who use IUD orTL؛ informed consent to participate in the study exclusion: history of allergic reaction to finasteride drug؛ pregnancy or trying to have a child؛ active infectionor any scratches and wounds in the scalp

Intervention groups

Group A will use finasteride in oral form and group B will use the topical form of finasteride nano liposomal solution 0.1% once a day.

Main outcome variables

The rate of improvement of hair loss; dht serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220901055844N1**
Registration date: **2023-12-19, 1402/09/28**
Registration timing: **prospective**

Last update: **2023-12-19, 1402/09/28**
Update count: **0**

Registration date

2023-12-19, 1402/09/28

Registrant information

Name
Roya Radanfar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3230 1542
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roya.radanfar72@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-10, 1402/10/20

Expected recruitment end date

2024-08-02, 1403/05/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the therapeutic effect of topical finasteride with oral finasteride in patients with androgenetic alopecia .

Public title

A comparative study of the therapeutic effect of topical finasteride with oral finasteride in patients with androgenetic alopecia .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having androgenic alopecia grade 2 to 5 based on the Norwood Hamilton classification in men Age above 18 years Not receiving treatment for androgenic alopecia during the last 3 months Having androgenetic alopecia grade 2 to 3 according to Ludwig grading in women Menopausal women or women over 18 years of age who use IUD or TL. Informed consent to participate in the study

Exclusion criteria:

Failure to sign the consent form. History of allergic reaction and anaphylaxis to Finasteride drug Pregnancy or trying to have a child. Individual history of infertility Active infection or any scratches and wounds in the scalp

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

The design will be done in parallel (assignment of two groups). The randomization of the design will be done by the restricted randomization method, the permuted block randomization type will be used, and a random sequence will be created using the random allocation software. Replacement blocks of 4 are assigned to two treatments (groups A, b). So that at least 14 people are treated with oral finasteride and at least 14 people are treated with topical finasteride.

Blinding (investigator's opinion)

Single blinded

Blinding description

Blinding will be done in such a way that two types of drugs will be provided to the patients by the second colleague of the resident of the project, and the collection of information before, three months after and 6 months after will be done by the resident of the project, who is not aware of the type of drug. Plan; The data with the name of the group will be provided to the consultant professor

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shahid fagihi hospital, zand ave, Shiraz

City

Shiraz

Province

Fars

Postal code

7134846114

Approval date

2023-04-15, 1402/01/26

Ethics committee reference number

IR.SUMS.MED.REC.1402.031

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

The rate of improvement in hair growth

Timepoint

evaluating the improvement of hair loss at the beginning of the study and at the end of 3months and at the end of 6months

Method of measurement

Comparison of the effect of topical finasteride with oral finasteride in the treatment of androgenic hair loss. how to measure this variable is with a questionnaire.

2

Description

Serum Dihydrotestosterone

Timepoint

At the beginning of the study and at the end of 6 months

Method of measurement

by free blood sampling from the patient at the Motahari clinic in Shiraz byuse a lab kit to measure blood Dihydrotestosterone

3

Description

Investigation of drug side effects

Timepoint

At the end of the 3rd month and the end of the 6th month

Method of measurement

At each stage, unwanted side effects, including redness, itching and symptoms of drug reaction, as well as breast tenderness, and symptoms of sexual dysfunction, are asked from the patients and recorded in the questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In group A, finasteride drug in oral form will be used. In this group, finasteride 1 mg tablets will be prescribed daily for male patients and 5 mg tablets manufactured by Ati Pharmed pharmaceutical company for female patients. In group B, the topical form of finasteride nano liposomal solution 0.1% will be used once a day. Finasteride nanoliposomes were prepared using the formulation prepared in the approved design and thesis of Dr. Mehyar Dari Gio under number 940768 at Mashhad University of Medical Sciences.will be. Then the properties of finasteride-containing nanoliposomes including particle size and zeta potential by DLS device.Morphology will be checked by electron microscope and stability on day 0, 1, 3, 6, 12 and 24 months at ambient temperature and 4 degrees, 25 and 37 degrees (according to ICH protocol.)which is sprayed on the surface of the area by the plastic applicator that comes with the product and massaged gently. Also, the patient will be warned not to wash the area for several hours after use, and to spray a little amount on the scalp and avoid a large amount. In order to use the same drug for the same patient on different days or for different patients, standard sprays were used, where every 12 to 15 puffs is equivalent to using 1 ml of the desired lotion.The duration of treatment in both groups is 6 months. And the visits of patients in both groups will be done at the beginning of the study and in the 3rd month and in the 6th month. Medicines are sent to the laboratory of Motahari Clinic in Shiraz for blood sampling, and the serum DHT levels will be checked for free before and after the start of treatment and after the end of 6 months of treatment. In order to comply with the blinding in the study, the resident is responsible for visiting and following up the response to the treatment in two groups and collecting information, they will not know the type of treatment given to the patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology clinic, Shahid Faghihi Hospital

Full name of responsible person

Roya Radanfar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammadhashem Hashempur

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Mehdi Ghahartars

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Roya Radanfar

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dermatology

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Person responsible for updating data

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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The results of the study are shared

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
The data of the study is made available to all people who are engaged in this industry

Under which criteria data/document could be used
There are no conditions

From where data/document is obtainable

via email Roya.Radanfar72@gmail.com

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

From the time of sending the request by email for one month

Comments