Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Comparison of the effectiveness of SLN containing finasteride and finasteride tablets in androgenic alopecia

Protocol summary

Study aim
Effect of topical SLN containing finasteride on androgenic alopecia

Design
Clinical trial with 25 controls and 25 intervention groups, parallel, single blind, randomized with random numbers table

Settings and conduct
Dermatology Clinic of Imam Reza Hospital Hospital (Mashhad University of Medical Sciences) Single blind: prescribe and drug evaluation is done by two different people. So that the evaluator does not know which patient is in which group. As the patient will find out whether the tablet can be taken or the solution, this study can not be considered as a double blind. The two groups, the first group, received topical 0.1% finasteride in the form of SLN with 5% localized minoxidil, and the second group received 5% minoxidil with finasteride 1 mg tablet.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Male patients aged 18-45 years with androgenic alopecia according to the Hamilton-Norwood criteria (Stages 2 to 4) Non-inclusion criteria: Iron supplements, iron deficiency anemia, thyroid and systemic diseases including lupus, Areata Alopecia, arthritis and and taking medications that cause hair loss, psychiatric illnesses, history of alcohol abuse or drug abuse, history of use of finasteride in the last 6 months, and minoxidil in one month In the past, patients with skeletal dysfunctions, seriously Cardiovascular, kidney, liver disease, history of hypersensitivity to medication, surgical history for the treatment of hair loss Exclusion criteria: Report of skin irritation, Failure to cooperate in the correct use of the drug and uncommon side effects of Finasteride

Intervention groups
The first group: topical 0.1% finasteride as SLN with 5% localized minoxidil the second group: 5% minoxidil with 1 mg finasteride tablet

Main outcome variables
The number, thickness and cumulative density of hair in the area of assessment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181128041780N1**
Registration date: **2019-06-30, 1398/04/09**
Registration timing: **retrospective**

Last update: **2019-06-30, 1398/04/09**
Update count: **0**

Registration date
2019-06-30, 1398/04/09

Registrant information

Name
shiva golmohammadzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3180 1323

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-11-30, 1397/09/09

Expected recruitment end date
2019-01-29, 1397/11/09

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of SLN containing finasteride and finasteride tablets in androgenic alopecia

Public title

Effect of SLN containing finasteride on anderogenic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Men with Androgenic Alopecia Based on Hamilton's Criteria. Stage 2-4 Completing the consent form

Exclusion criteria:

No endocrine disease (diabetes), thyroid disorders, systemic diseases including lupus, other cases, including arthritis and cicatrisil (associated with scar), history of skin or systemic malignancy, psychiatric disorders, skin disorders Head skulls other than those with AGASerious Cardiovascular Diseases, Kidney Disease, Liver Disease No use of zinc and iron supplements, malnutrition, iron deficiency anemia Non-use of medications leads to hair loss, including anti-hypertensive and anti-inflammatory drugs, NSAIDs No history of alcohol consumption or substance abuse No history of finasteride in the last 6 months and minoxidil in the past month No history of drug hypersensitivity, breast disorders, surgical history for the treatment of hair loss

Age

From **18 years** old to **45 years** old

Gender

Male

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomized random numbered table

Blinding (investigator's opinion)

Single blinded

Blinding description

Drug administration and drug evaluation are performed by two different individuals, so that the person evaluating is not aware of which patient is in the group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Central Building of Mashhad University of Medical Sciences (Ghorshi),Daneshgah 16, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2018-10-20, 1397/07/28

Ethics committee reference number

IR.MUMS.REC.1397.210

Health conditions studied

1

Description of health condition studied

anderogenic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

The number of hair from short hair in 1 cm square in the area of assessment in the Vertex hairless part

Timepoint

At the beginning of the work and weeks 8, 16 and 24

Method of measurement

Using the computer scan obtained from macrophotography images of the marked area, it is evaluated for hair growth.

Secondary outcomes

1

Description

1- Evaluation of the frequency of local skin complications including: erythema-burning-itchy-folliculitis-clinical diagnosis by the assessor

Timepoint

At the beginning of the work and weeks 8, 16 and 24

Method of measurement

1-Measuring erythema and itching and burning with a visual analogue scale and evaluating folliculitis clinically and by assessor.

2

Description
2. Quality of life assessment
Timepoint
At the beginning of the work and weeks 8, 16 and 24
Method of measurement
2. Assessing the quality of life ,the basis of the WAA-QOL benchmark.

Intervention groups

1

Description
Intervention group: In the first group, 5% localized minoxidil twice a day, any time 1 cc with a 0.1% finasteride topical form, as SLN, once a day, any time 1 cc.
Category
Treatment - Drugs

2

Description
Control group: The topical solution of minoxidil 5% is given twice daily, any time 1 cc, with one tablet of finasteride 1 mg per day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology clinic, Imam Raza Hospital
Full name of responsible person
sama gharaei
Street address
Imam Reza Hospital, Imam Reza square, Ebn_e_sina Avenue
City
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9137913316
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2

Recruitment center
Name of recruitment center
Dermatology clinic,ghaem hospital
Full name of responsible person
sama gharaei
Street address
Ahmadabad street, beside the Parastar street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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ramresearch@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
sama gharaei
Position
student of pharmacy
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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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
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
Undecided - It is not yet known if there will be 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