# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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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**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
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**2**

**Recruitment center**
**Name of recruitment center**
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sama gharaei
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## Sponsors / Funding sources

**1**

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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**
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**Position**
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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