

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparison of the efficacy of Spironolcatone 5% and Progesterone 2% on hair density and diameter in female pattern androgenetic alopecia

#### Protocol summary

##### Summary

The purpose of this study is to compare the effectiveness of topical spironolactone five percent with progesterone two percent in the treatment of patients with grade one or two female pattern androgenetic alopecia. This is a randomized; double-blind trial without a placebo and single center study. 72 patients diagnosed with grade one or two androgenetic alopecia will be enrolled in this study; patients will be randomized in two parallel groups. After obtaining informed consent from patients; patients will be divided into two groups. Group of patients will be treated for 24 weeks with spironolactone five percent and progesterone two percent. The patients will be examined bi monthly for 6 months. The examination will be included measurement of hair density per squared centimeters and hair diameter. Criteria for improvement; will be the increase hair numbers or increase hair diameter.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201512252581N4**

Registration date: **2016-12-14, 1395/09/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-14, 1395/09/24

##### Registrant information

###### Name

Hamide Herizchi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1336 4650

###### Email address

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###### Recruitment status

**Recruitment complete**

###### Funding source

Tabriz University of Medical Sciences

###### Expected recruitment start date

2015-12-22, 1394/10/01

###### Expected recruitment end date

2016-06-20, 1395/03/31

###### Actual recruitment start date

empty

###### Actual recruitment end date

empty

###### Trial completion date

empty

###### Scientific title

Comparison of the efficacy of Spironolcatone 5% and Progesterone 2% on hair density and diameter in female pattern androgenetic alopecia

###### Public title

Comparison of the efficacy of Spironolcatone 5% and Progesterone 2% on hair density and diameter in female pattern hair loss

###### Purpose

Treatment

###### Inclusion/Exclusion criteria

Inclusion criteria: female; grade 1 or 2 androgenetic alopecia; no underlying hormonal disorders Exclusion criteria: patient's decision to exit the study; underlying hormonal disorder; anemia; use of topical medications in the past week; taking oral medications in the past four weeks; have allergy to spironolactone or progesterone; pregnancy or planning to pregnancy or breastfeeding

###### Age

No age limit

**Gender**

Female

**Phase**

4

**Groups that have been masked**

No information

**Sample size**

Target sample size: 36

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double 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**

Third floor, Tabriz Medical Sciences University, Gholgasht ave

**City**

Tabriz

**Postal code**

**Approval date**

2015-06-08, 1394/03/18

**Ethics committee reference number**

tbzmed.rec.138.222

**Health conditions studied**

1

**Description of health condition studied**

Female pattern androgenetic alopecia

**ICD-10 code**

L64

**ICD-10 code description**

Androgenic alopecia

**Primary outcomes**

1

**Description**

Hair density per squared cm, Hair diameter

**Timepoint**

At baseline, 8th, 16th ,24th weeks

**Method of measurement**

Trichoscopy

**Secondary outcomes**

1

**Description**

Side effects

**Timepoint**

At baseline, 8th, 16th and 24th weeks

**Method of measurement**

Qualitative

**Intervention groups**

1

**Description**

Control group; Topical 2% Progesterone solution, twice a day for 24 weeks

**Category**

Treatment - Drugs

2

**Description**

Intervention group; Topical 5% Spironolactone solution, twice a day for 24 weeks

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Sina Hospital, Dermatology clinic

**Full name of responsible person**

Herizvhi ghadim Hamideh

**Street address**

Sina Hospital, Dermatology department

**City**

Tabriz

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research, Tabriz University of Medical Sciences

**Full name of responsible person**

Rashidi Mohammad Reza

**Street address**

Golgasht Ave., Daneshgah St., Tabriz, Iran

**City**

Tabriz  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Vice Chancellor for research, Tabriz University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**  
*empty*  
**Domestic or foreign origin**  
*empty*  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Herizchi ghadim Hamideh  
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Dermatologist, associate professor  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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Zeinolabedin zadeh Vahideh  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

*empty*

### Study Protocol

*empty*

### Statistical Analysis Plan

*empty*

### Informed Consent Form

*empty*

### Clinical Study Report

*empty*

### Analytic Code

*empty*

### Data Dictionary

*empty*