Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of topical solution of Finasteride 0/2% versus topical solution of Minoxidil 5% in the treatment of Androgenic Alopecia in men, A Randomized, Double-Blind, Clinical Trial

Protocol summary

Study aim
Determining and comparing the effect of two drugs, topical solution of Finasteride 0/2% and topical solution of Minoxidil 5% in the treatment of Androgenetic Alopecia in men.

Design
Clinical trial with control group, with parallel groups, Double blind, Random, phase 2 on 200 patients, for randomization, method alternate was used.

Settings and conduct
Patients are randomly divided into two groups of 100 people. Receive as one among bottles A and B. After daily use according to the instructions, they are monitored on a monthly basis and a checklist for each patient is completed at each visit. This process lasts up to 6 months. Monthly visit is done in the Dermatology Clinic of Imam Reza Hospital in Ardabil on sundays and wednesdays every week. During this study, neither the patient nor the attending physician was aware of the contents of the bottle prescribed to the patient and at the end of the study, after collecting and analyzing the data, the nature of bottles A and B will be determined.

Participants/Inclusion and exclusion criteria
If there is more than a week between medications, the patient will be excluded from the study. Patients under study during these six months should not use any other drugs (traditional and industrial), either topically or systemically because If used, they will be excluded from the study.

Intervention groups
Patients are randomly divided into two groups of 100 people.To a group (intervention) bottle containing 25 cc of 0/2% topical Finasteride solution and the second group (control) is given 25 cc of 5% Minoxidil topical solution. Patients should be examined monthly.

Main outcome variables
The number of hairs plucked in the Pull test; Active areas for Alopecia

General information

Reason for update
Change in the percentage of Finasteride (from 2% to 0.2%) due to a mistake in entering the initial information.

Acronym

IRCT registration information
IRCT registration number: **IRCT20191023045213N1**
Registration date: **2020-08-19, 1399/05/29**
Registration timing: **prospective**

Last update: **2020-09-01, 1399/06/11**
Update count: **1**

Registration date
2020-08-19, 1399/05/29

Registrant information

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Amir Sadrinia

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2020-10-20, 1399/07/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of topical solution of Finasteride 0/2% versus topical solution of Minoxidil 5% in the treatment of Androgenic Alopecia in men, A Randomized, Double-Blind, Clinical Trial

Public title
The effect of Finasteride solution on male hair loss
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Volunteer to participate in the study
Exclusion criteria:
Age
No age limit
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, there will be two types of dark bottles, one named A and the other B. In one type of bottle 25 ml of Finasteride 0/2% topical solution and in the second type 25 ml of Minoxidil 5% topical solution are poured. The patients were randomly divided into two groups of 100 each and In the first stage, they are subjected to a Pull test, which is an important test to determine the active sites of Alopecia and In it 60-70 pieces of patient hair are grabbed and pulled hairs are counted and If the number of plucked hairs is more than 6-7, the test is positive and the area of the head is considered as the active site for Alopecia and its subsequent monthly examination. In subsequent monthly examinations, those points on the head will be tested for loss. Then, one group is given bottle A and the other group is given bottle B. The patient should apply 15 drops of these solutions on his head every 12 hours and at the end of each month, go to the clinic for a checkup. In the monthly examination, patients also undergo a pull test and the number of hairs plucked in the test is recorded, until the end of the sixth month, which is the end of treatment. If the patient runs out of medicine during this time, he will receive a bottle with the same name as the first bottle, and if he forgets to use his medication on time, he should use his medication immediately after being reminded, but if there is a gap of more than a week between taking the drug the patient will be excluded from the study. Patients under study should not use any other drugs (traditional and industrial) during these six months, either topically or systemically as they will be excluded if the study is used, If used, they will be excluded from the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
During this study, a dermatologist as the head of the research group in the clinic, after explaining the working method for patients and possible problems during the research period for patients, if he volunteers, he puts them in the study. In order to start treatment, they enter group A or B as one of the volunteer patients. After assigning the checklist to each patient (according to the entered group), the patient receives bottles containing the treatment solution (A or B) from the head of the clinic according to his checklist. During this process, neither the specialist physician nor the clinic manager nor the patient don't knows the contents of the therapeutic bottle and which group of bottles are Finasteride or Minoxidil. Therapeutic bottles are made by a pharmacologist in the university laboratory and poured into bottles and then transported to the clinic of the study. The pharmacologist is the only person who knows the contents of the bottles and during the study and analysis of the data has nothing to do with the dermatologist and the head of clinic and the analyzer and patients. After the end of sampling and the end of the 6-month treatment period, by analyzing the data, the analyzer presents the information in the form of an initial grouping, and at the end of the analysis, the nature of the bottles will be determined by a pharmacologist.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ardebil University of Medical Sciences
Street address
Daneshgah Ave
City
Ardebil
Province
Ardabil
Postal code
5618985991
Approval date
2020-06-01, 1399/03/12
Ethics committee reference number

IR.ARUMS.REC.1399.148

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
Pull test score
Timepoint
Monthly
Method of measurement
Physical exam

Secondary outcomes

empty

Intervention groups

1

Description
Control group: After receiving a topical solution of Minoxidil and taking the drug every 12 hours 15 mg, they are included in the study and examined monthly.
Category
Treatment - Drugs

2

Description
Intervention group: After receiving a topical solution of Finasteride and taking it according to Minoxidil, they are included in the study and examined monthly
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ardebil's Imam Reza hospital
Full name of responsible person
Majid Rostami Moghadam
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Sponsors / Funding sources

1

Sponsor
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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
Ardabil 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
Ardabil University of Medical Sciences
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Position
Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is potentially shareable after unidentified individuals.
When the data will become available and for how long
Access started from 1401
To whom data/document is available
Researchers working in academic and scientific institutions.
Under which criteria data/document could be used
If the purpose of access is to investigate possible bugs in the study.
From where data/document is obtainable
Amir Sadrinia Email address: sadriamir73@gmail.com
What processes are involved for a request to access data/document
As soon as the email is sent to the mentioned address, the information will be sent with the confirmation of the purpose.
Comments