Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the therapeutic effect of intralesional injection of botulinum toxin with placebo in patients with androgenetic alopecia receiving finasteride tab

Protocol summary

Study aim

Determine and comparison of the therapeutic effect of botulinum toxin intralesional injection with placebo in men with androgenic alopecia receiving finasteride tablets

Design

Clinical trial with control group and parallel group, double blind, randomized, phase 3 on 48 patients. A Block randomization was used for randomization.

Settings and conduct

The participants are patients with androgenic alopecia referring to Shahid Faqihi Skin Clinic in Shiraz and Imam Reza Clinic in Shiraz. All patients will be given finasteride tablets, and based on a permutation block of 4, one of the groups will be injected with Botox and the other with a placebo prepared by the project partner and the participant, clinical caregiver, researcher and the person responsible for evaluating the treatment will not know about it.

Participants/Inclusion and exclusion criteria

Male patients over 18 years of age with androgenetic hair loss grade 3 to 5 who have not received treatment in the last 3 months and are not suffering from systemic diseases and are not receiving immunosuppressive drugs and do not have injection site infections are included in the study.

Intervention groups

In group A, the combination of botulinum toxin and finasteride tablets will be used. In this group, daily finasteride 1 mg tablets manufactured by Soha Pharmaceutical Company will be prescribed for patients, as well as 150 units of botulinum toxin type A Masport 500 units (Masoun Daro Company) with 5 ml of diluted normal saline in 30 places on the patients' heads (for Each point 5 units) is injected with an insulin syringe. In group B, patients will receive 1 mg finasteride tablets made by Soha Pharmaceutical Company daily, and instead of botulinum toxin, 1.5 ml of normal saline will be injected in 30 points of the patient's head with an insulin syringe.

Main outcome variables

hair density

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191013045092N3**
Registration date: **2022-09-18, 1401/06/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-09-18, 1401/06/27**
Update count: **0**

Registration date

2022-09-18, 1401/06/27

Registrant information

Name
Ladan Dastgheib
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 71 3231 9049
Email address
dastghl@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-25, 1401/05/03

Expected recruitment end date

2023-02-22, 1401/12/03

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the therapeutic effect of intralesional injection of botulinum toxin with placebo in patients with androgenetic alopecia receiving finasteride tab

Public title
Comparison of the therapeutic effect of intralesional injection of botulinum toxin with placebo in patients with androgenetic alopecia receiving finasteride tab
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. Being male and older than 18 years 2. Suffering from androgenic alopecia grade 3 to 5 based on the Norwood Hamilton classification and Not receiving treatment for androgenic alopecia during the last 3 months
Exclusion criteria:
1. Severe diseases of internal organs, eyes or skin 2. Diseases of the neuromuscular system 3. Inflammation, infection or unhealed wounds on the skin around the injection site on the head 4. Receiving systematic treatment with corticosteroids or other immunosuppressants and immune modulators in the last 3 months 5. Receiving anticoagulant and antiplatelet drugs 6. Hair transplantation in the past 7. Infectious underlying disease, autoimmune, malignancy 8. Phobia about treatment with botulinum toxin 9. Reluctance to continue Study participation during treatment and follow-up
Age
From **18 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be assigned to one of two groups A and B based on block randomization. Medicines will be provided to the patient in an envelope based on the specified group. In one group, daily Finasteride 1 mg tablets manufactured by Soha Pharmaceutical Company will be prescribed, as well as 150 units of botulinum toxin type A Masport 500 units of Masoun Daro Company with 5 ml of diluted normal saline in 30 points on the patients' heads (for each point 5 units) is injected by insulin syringe. In the second group, the patients will be prescribed 1 mg finasteride tablets made by Saha Pharmaceutical Company daily, and instead of botulinum toxin, 1.5 ml of normal saline will be injected in 30 points of the patient's head with an insulin syringe.
Blinding (investigator's opinion)
Double blinded
Blinding description
Finasteride tablets will be given to all patients, but the intralesional injectable drug (Botox or placebo) will be prepared by the design partner and will be specified in two envelopes A and B based on random groups and will be given to the clinical caregiver for injection. Therefore, neither the participant nor the clinical caregiver, the researcher and the outcome assessor will know about the type of substance injected.
Placebo
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
Shiraz University of Medical Sciences, Zand St., Shiraz. Iran
City
Shiraz
Province
Fars
Postal code
7134845794
Approval date
2022-07-16, 1401/04/25
Ethics committee reference number
IR.SUMS.MED.REC.1401.217

Health conditions studied

1

Description of health condition studied
male androgenetic alopecia
ICD-10 code
L64
ICD-10 code description
Androgenic alopecia

Primary outcomes

1

Description
Hair density
Timepoint
Measurement of hair density at the beginning of the study and at the end of month 3 and at the end of month 6
Method of measurement
Photographing with a visioface 1000 D device

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, daily finasteride 1 mg tablets manufactured by Soha Pharmaceutical Company will be prescribed for patients, as well as 150 units of botulinum toxin type A Masport 500 units (Masoun Daru Company) with 5 ml of diluted normal saline in 30 places on the patients' head (for Each point 5 units) is injected with an insulin syringe.
Category
Treatment - Drugs

2

Description
Control group: In the control group, the patients will receive 1 mg finasteride tablets made by Soha Pharmaceutical Company daily, and instead of botulinum toxin, 1.5 ml of normal saline will be injected in 30 points of the patient's head with an insulin syringe.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dermatology Clinic of Shahid Faqihi Hospital, Shiraz
Full name of responsible person
Ladan Dastgheib
Street address
karim khan zand st
City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3235 1087
Fax
Email
FaghihiHsp@sums.ac.ir
Web page address
https://faghihi.sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Memarpour
Street address
Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134814336
Phone
+98 71 3212 2430
Email
vcrdep@sums.ac.ir
Web page address
https://research.sums.ac.ir
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
Dr. Ladan Dastgheib
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology

Street address
Dermatology Department, floor 3, Shahid faghihi hospital,Karim khan zand street, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3231 9049
Email
dastgh@sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ladan Dastgheib
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Dermatology Department, floor 3, Shahid faghihi hospital,Karim khan zand street, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3231 9049
Email
dastgh@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ladan Dastgheib
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Dermatology
Street address
Dermatology Department, floor 3, Shahid faghihi hospital,Karim khan zand street, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3231 9049
Email
dastgh@sums.ac.ir

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
article
When the data will become available and for how long
article publication time
To whom data/document is available
researchers
Under which criteria data/document could be used
In order to raise the scientific level of researchers in this field through articles
From where data/document is obtainable
executor of plan
What processes are involved for a request to access data/document
Submit request, review project manager and send feedback
Comments