

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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 Faqih 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