

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

A comparative study of the results of using botulinum toxin by different doses in women suffering from androgenic alopecia .

Protocol summary

Study aim

A comparative study of the results of using botulinum toxin by different doses in women suffering from androgenic alopecia who referred to Razi Skin Hospital from 1401 to 1402

Design

Clinical trial with control group, and parallel groups, double-blind, randomized study.

Settings and conduct

This study is a double-blind, randomized clinical trial. Women suffering from androgenic alopecia referring to the skin clinic of Razi Hospital who meet the inclusion criteria are studied. Patients are treated with Minoxidil 5% and botulinum(Masport) in three groups with a standard protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Patients with grade 2/3/4 based on SINCLAIR SCALE for disease severity. 2- Having the ability for regular followup visits. 3- Not receiving treatment in the last 3 months 4- age between 18-55 5- Not having contraindications for using minoxidil or botulinum toxin . Exclusion criteria: 1- Having needle phobia. 2- Having alopecia areata and another hair diseases(LPP). 3- Having neuromuscular disease. 4- Previous use of corticosteroids or immunosuppressive drugs in the last 3 months. 5- Having localized infection. 6- Having internal systemic and skin disease or localized dermatosis. 7- Patients with a history of bleeding diseases or under treatment with anticoagulants . 8- Previous family or personal history of keloid. 9- Having koebner phenomenon. 10- Having symptoms of hyperandrogenism and in need for systemic drugs. 11- pregnancy and lactation. 12- Another treatments in less than 3 months.

Intervention groups

Control group: using minoxidil solution 5% with normal saline injection Intervention group: using minoxidil 5% solution with the injection of 100 units botulinum toxin (Masport) Intervention group: using minoxidil 5% solution with the injection of 200 units botulinum toxin(Masport)

Main outcome variables

hair volume and density

General information

Reason for update

I want to add a second sponsor for my trial(MDPC masoondarou pharmaceutical company) and the trade name for the botulinum toxin that will be used (Masport)

Acronym

IRCT registration information

IRCT registration number: **IRCT20221016056203N1**

Registration date: **2022-11-19, 1401/08/28**

Registration timing: **prospective**

Last update: **2022-12-18, 1401/09/27**

Update count: **1**

Registration date

2022-11-19, 1401/08/28

Registrant information

Name

Hawraa Taleb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5563 0553

Email address

hawraa-taleb@outlook.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the results of using botulinum toxin by different doses in women suffering from androgenic alopecia .

Public title
studying the effect of botox on hormonal female hair loss

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with grade 2/4/3 based on SINCLAIR SCALE for disease severity having the ability for regular visits Not receiving previous treatment in the last three months age between 18-55 not having contraindication for minoxidil 5% and botulinum toxin
Exclusion criteria:
Having needle phobia Having alopecia areata and another hair diseases(LPP) Having neuromuscular disease Previous use of corticosteroids or immunosuppressive drugs in the last 3 months Having localized infection Having internal systemic and skin disease or localized dermatosis. Patients with a history of bleeding diseases or under treatment with anticoagulants Previous family or personal history of keloid Having koebner phenomenon Having symptoms of hyperandrogenism and in need for systemic drugs pregnancy and lactation Another treatments in less than 3 months.

Age
From **18 years** old to **55 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **63**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized assignment of individuals to treatment and controls groups. simple with sealed envelopes containing the material .

Blinding (investigator's opinion)
Double blinded

Blinding description
Double blinded The patient receives the injection substance (intervention or control group) in sealed envelopes that are coded. Coding is done by one of the collaborators of the project and the evaluator and the patient are blinded

Placebo

Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
No 82 , Behzad sedakat intersection ,Zhiyan Panah street .
City
Tehran
Province
Tehran
Postal code
1111111111

Approval date
2022-10-22, 1401/07/30

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.551

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
Hair volume and density in qualitative and quantitative way

Timepoint
3 and 6 months after starting treatment

Method of measurement
photography - photo finder - dermoscopy -self assessment

Secondary outcomes

empty

Intervention groups

1

Description

Control group: using minoxidil solution 5% with normal saline injection

Category

Treatment - Drugs

2

Description

Intervention group: using minoxidil 5% solution with the injection of 100 units botulinum toxin (Masport)

Category

Treatment - Drugs

3

Description

Intervention group: using minoxidil 5% solution with the injection of 200 units botulinum toxin (Masport).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Hawraa Taleb

Street address

No 82 , Behzad sedakat intersection ,Zhiyan Panah street .

City

Tehran

Province

Tehran

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Phone

+98 922 231 3954

Email

hawraa-taleb@outlook.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Mariam Nasimi

Street address

No 82 , Behzad sedakat intersection ,Zhiyan Panah street

City

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Email

hawraa-taleb@outlook.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Masoondarou pharmaceutical Company MDPC

Full name of responsible person

Naser mohammadpour

Street address

No 82 , Behzad sedakat intersection ,Zhiyan Panah street

City

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Phone

+98 922 231 3954

Email

hawraa-taleb@outlook.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Masoondarou pharmaceutical Company MDPC

Proportion provided by this source

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

hawraa-taleb@outlook.com

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hawraa Taleb

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No 82 , Behzad sedakat intersection ,Zhiyan Panah street

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Safoura Shakoei Nejad

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Email

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hawraa Taleb

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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City

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Phone

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Individual information about the disease will be confidential and will be shared in general about the effect of the treatment on all patients

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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