

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparative efficacy study of microneedling (2 different depth of penetration) and topical minoxidil versus topical minoxidil alone in androgenetic alopecia in patients referring to educational center of Isfahan university of medical sciences

Protocol summary

Study aim

To assess the efficacy of combined microneedling (with two different depth of penetration) and topical minoxidil in the treatment of moderate to severe androgenetic alopecia (AGA) compared with topical minoxidil alone

Design

Randomized, double-blind, parallel group clinical trial of sixty patients with one control group and two intervention groups. Randomization is attained using a random digit table.

Settings and conduct

Patients with clinically diagnosed AGA, from the attendants of the Dermatology Outpatient Clinic of Alzahra Hospital, are randomly divided into 3 groups. All patients receive topical minoxidil but microneedling procedure (a total of six sessions with 2 weeks intervals) is applied only for 2 of three groups with different depth of needle in each group. Patients and investigators who collect post treatment data are not informed about group allocations.

Participants/Inclusion and exclusion criteria

Men and women between 18 years and 45 years of age with moderate to severe AGA are enrolled in this study. Patients with major systemic diseases; other forms of alopecia; skin disorders with risk of Koebner phenomenon; history of bleeding disorders; active infection at the scalp; keloidal tendency, pregnant and lactating women and patients with use of systemic medications for hair regrowth within last 6 months are not included in this study.

Intervention groups

Patients in control group are treated with topical 5% minoxidil lotion, applied twice daily for 12 weeks. patients in other two groups are instructed to apply minoxidil in a similar dose and will receive microneedling procedure at 2-weeks intervals for a period of 12 weeks.

Depth of penetration is set at 1.2 mm for one group and 0.6 mm for the other one.

Main outcome variables

Pre-treatment and post treatment hair count and hair thickness; patients' satisfaction score and investigator's score based on photographs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191203045592N1**

Registration date: **2020-01-03, 1398/10/13**

Registration timing: **retrospective**

Last update: **2020-01-03, 1398/10/13**

Update count: **0**

Registration date

2020-01-03, 1398/10/13

Registrant information

Name

Samin Nabavinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3131 7715

Email address

saminstrs@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01
Expected recruitment end date
2019-02-20, 1397/12/01
Actual recruitment start date
2018-08-23, 1397/06/01
Actual recruitment end date
2019-03-06, 1397/12/15
Trial completion date
2019-05-22, 1398/03/01

Scientific title

Comparative efficacy study of microneedling (2 different depth of penetration) and topical minoxidil versus topical minoxidil alone in androgenetic alopecia in patients referring to educational center of Isfahan university of medical sciences

Public title

Microneedling in androgenetic alopecia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with moderate to severe androgenetic alopecia
Patients who have not used systemic medications that influence hair growth within the past 6 months

Exclusion criteria:

Patients with other forms of alopecia, such as telogen effluvium and alopecia areata
Patients with history of bleeding disorders
Patients with keloidal tendency
Patients with active infection at the microneedling site
Patients with skin dermatosis with risk of Koebner phenomenon, such as psoriasis and lichen planus
Pregnant and lactating women
Patients with any major systemic disease

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **59**

Randomization (investigator's opinion)

Randomized

Randomization description

Each patient will be assigned a number from 01 to 60. Then we randomly choose a spot on the random digit table. we use the first 2 digits of the numbers on the chart (since we have a population of 60 patients) and document the first 20 numbers that are less than 61. Patients with these numbers are allocated to control group. Patients with the next 20 numbers collected from the chart, are allocated to microneedling group with a depth of 1.2 mm. the rest of the patients belong to the third group(microneedling with a depth of 0.6 mm).

Patients are not aware of group allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in control group are treated with topical minoxidil solution alone. Patients in other two groups receive microneedling procedure other than topical minoxidil but depth of needle penetration is different between these two groups and patients are not aware of needle depth of penetration used for them. A second investigator compares pre treatment and post treatment photographs of patients and evaluates data collected from hair analysis system while he does not know which experimental group patient belongs to.

Placebo

Not used

Assignment

Parallel

Other design features

Three experimental groups are evaluated in this study. All patients receive a topical drug with a similar dose. patients in two intervention groups receive microneedling procedure with different settings ,other than topical solution.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

No. 301,Shadab complex, Shadab Alley, Bijan Fotouhi Alley, Mohtasham kashani Street

City

Isfahan

Province

Isfahan

Postal code

8175967622

Approval date

2019-02-14, 1397/11/25

Ethics committee reference number

IR.MUI.MED.REC.1397.233

Health conditions studied

1

Description of health condition studied

Androgenetic alopecia

ICD-10 code

L64

ICD-10 code description

Androgenic alopecia

Primary outcomes

1

Description

Hair count

Timepoint

At start of study and 14 weeks

Method of measurement

Scalp & Hair Polarizing HMS System (KC Technology Company; Korea)

2

Description

Hair thickness

Timepoint

At start of study and 14 weeks

Method of measurement

Scalp & Hair Polarizing HMS System (KC Technology Company; Korea)

3

Description

Patient's satisfaction score

Timepoint

At 14 weeks

Method of measurement

The standardized 7 point rating scale (-3 = greatly decreased, -2 = moderately decreased, -1 = slightly decreased, 0 = no change, +1 = slightly increased, +2 = moderately increased, +3 = greatly increased)

4

Description

Investigator's assessment based on changes in standard photographs

Timepoint

Standard photography at base line and at 14 weeks

Method of measurement

The standardized 7 point rating scale (-3 = greatly decreased, -2 = moderately decreased, -1 = slightly decreased, 0 = no change, +1 = slightly increased, +2 = moderately increased, +3 = greatly increased)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Use 1 CC of topical 5% minoxidil lotion (Pakdarou co., Tehran, Iran) applied twice daily for 12 weeks

Category

Treatment - Drugs

2

Description

Intervention group no.1: Use 1 CC of topical 5% minoxidil lotion (Pakdarou co., Tehran, Iran) applied twice daily for 12 weeks as well as 6 sessions of microneedling procedure with a microneedle depth of 1.2 mm, at 2-weeks intervals

Category

Treatment - Devices

3

Description

Intervention group no.2: Use 1 CC of topical 5% minoxidil lotion (Pakdarou co., Tehran, Iran) applied twice daily for 12 weeks as well as 6 sessions of microneedling procedure with a microneedle depth of 0.6 mm, at 2-weeks intervals

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Gita Faghihi

Street address

No. 301,Shadab complex, Shadab Alley, Bijan Fotouhi Alley, Mohtasham kashani Street

City

Isfahan

Province

Isfahan

Postal code

8175967622

Phone

+98 31 3131 7715

Email

saminstrs@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoueyejavanmard

Street address

No. 301,Shadab complex, Shadab Alley, Bijan Fotouhi Alley, Mohtasham kashani Street

City

Isfahan

Province

Isfahan

Postal code

9676228175

Phone

+98 31 3131 7715

Email

saminstrs@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Samin Nabavinejad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No. 301,Shadab complex, Shadab Alley, Bijan Fotouhi Alley, Mohtasham kashani Street

City

Esfahan

Province

Isfahan

Postal code

8175967622

Phone

+98 31 3131 7715

Fax

Email

saminstrs@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Samin Nabavinejad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No. 301,Shadab complex, Shadab Alley, Bijan Fotouhi Alley, Mohtasham kashani Street

City

Esfahan

Province

Isfahan

Postal code

8175967622

Phone

+98 31 3131 7715

Fax

Email

saminstrs@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Samin Nabavinejad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No. 301,Shadab complex, Shadab Alley, Bijan Fotouhi Alley, Mohtasham kashani Street

City

Esfahan

Province

Isfahan

Postal code

8175967622

Phone

+98 31 3131 7715

Fax

Email

saminstrs@gmail.com

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

No information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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