Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 31 3131 7715

Email address
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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

Isfehan

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
Hail 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjouyejavanmard
Street address
No. 301,Shadab complex, Shadab Alley, Bijan Fotouhi Alley, Mohtasham kashani Street
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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
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

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Contact

Name of organization / entity
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Position
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Person responsible for updating data

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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
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