

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Investigation of the efficacy of topical latanoprost 0.005% combined with microneedling in comparison to microneedling in the treatment of the patients with scalp patchy alopecia areata

Protocol summary

Study aim

Determination of the efficacy of topical latanoprost 0.005% combined with microneedling in comparison to microneedling in the treatment of the patients with scalp patchy alopecia areata

Design

Phase 3, parallel group, clinical trial, with consecutive sampling, including 20 patients, double blinded, computerized randomized with permuted blocks

Settings and conduct

The study is conducted in the Imam Reza and Shahid Faghihi clinics of Shiraz University of Medical Sciences randomly with latanoprost combined with microneedling on patches of alopecia areata of one side of scalp (3 session every two week) and microneedling on patches of alopecia areata of the other side of scalp (3 session every two week). The patients are assessed at the beginning of treatment, every two week visits for procedure and 3 month after the first visit by photography and dermoscopy. The investigator and/or outcome assessor (both of them is attending) and patient are blind to the type of treatment.

Participants/Inclusion and exclusion criteria

The inclusion criteria include: 1. age > 18 years old 2. AA coverage < 25% of scalp surface 3. presence of 2-5 patches The exclusion criteria include: 1. allergy or hypersensitivity to any component of treatment products 2. pregnancy or lactation 3. progressive disease

Intervention groups

Intervention side: topical latanoprost combined with microneedling of patches of alopecia areata on one side of scalp three sessions every two week Control side: Microneedling of the patches of alopecia areata on opposite side of scalp three sessions every two week

Main outcome variables

terminal hair growth grade change; rate of patch size change; patient satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220316054304N1**

Registration date: **2022-09-05, 1401/06/14**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-05, 1401/06/14**

Update count: **0**

Registration date

2022-09-05, 1401/06/14

Registrant information

Name

Mehrnoosh Taheri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3648 4599

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xghazal1369x@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-03, 1401/06/12

Expected recruitment end date

2023-09-03, 1402/06/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the efficacy of topical latanoprost 0.005% combined with microneedling in comparison to microneedling in the treatment of the patients with scalp patchy alopecia areata

Public title

Effect of topical Latanoprost combined with microneedling in the treatment of alopecia areata

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age > 18 years old AA coverage < 25% of scalp surface presence of 2-5 patches discontinued of intralesional triamcinolone treatment at least 2 weeks earlier stable disease without the appearance of a new patch or increase in the size of the patches for at least 15 days

Exclusion criteria:

allergy or hypersensitivity to any component of treatment products pregnancy or lactation any skin infection on treatment area severe medical illness simultaneous use of immunosuppressant or anticoagulant medication progressive disease positive hair pull test

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: 20

More than 1 sample in each individual

Number of samples in each individual: 2

right side or left side patches will be received combined latanoprost with microneedling then opposite side will be received microneedling alone.

Randomization (investigator's opinion)

Randomized

Randomization description

The left or right sided patches are randomly allocated by block randomization method (block sizes: 4) to receive latanoprost combined microneedling. This randomization list is prepared by Random Allocation Software. Patients will be randomly assigned into 2 groups (A or B) of 10 patients by using this computer software, which is done before the first session by a neutral colleague. Group A will receive latanoprost combined microneedling on the patches of right side of scalp and just microneedling on the patches of left side of scalp. Group B will receive latanoprost combined microneedling on the patches of left side of scalp and just microneedling on the patches of right side of scalp. (Actually each participant is case and control simultaneously.)

Blinding (investigator's opinion)

Double blinded

Blinding description

this study is double-blinded. The investigator or outcome assessor (both of them is attending) is not present during doing procedures which is done by care provider. The patient is also unaware of applying latanoprost due to anesthesia induced by xyla-p. (Actually each participant is case and control simultaneously.)

Placebo

Not 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

2022-05-09, 1401/02/19

Ethics committee reference number

IR.SUMS.MED.REC.1401.072

Health conditions studied

1

Description of health condition studied

alopecia areata

ICD-10 code

L63.8

ICD-10 code description

other alopecia areata

Primary outcomes

1

Description

terminal hair growth change

Timepoint

The patients will be assessed in 2 every 2 weeks visits for procedures, and 3 months after the first visit.

Method of measurement

Terminal hair growth change grade into following 6 grade: Grade 0: no change or further hair loss / Grade 1:

regrowth of 1-24% terminal hair /Grade 2: regrowth of 25-49% terminal hair /Grade 3: regrowth of 50-74% terminal hair /Grade 4: regrowth of 75-99% terminal hair /Grade 5: regrowth of 100% terminal hair

Secondary outcomes

1

Description

rate of patch size change

Timepoint

The patients will be assessed in 2 every 2 weeks visits for procedures, and 3 months after the first visit.

Method of measurement

Rate of size change (%) = $\frac{\text{Baseline size} - \text{Follow up size}}{\text{Baseline size}} \times 100$

2

Description

patient satisfaction

Timepoint

The patients will be assessed in 2 every 2 weeks visits for procedures, and 3 months after the first visit.

Method of measurement

A 5-point scale. 4: Extremely satisfied, 3: Very satisfied, 2: satisfied, 1: Slightly satisfied, 0: Not satisfied

Intervention groups

1

Description

Intervention side: Under aseptic precaution microneedling is performed by Dr.pen ULTIMA-A6 manufactured in USA. The device is an automated microneedling device, with 12pins cartridge. The depth of penetration will be 2 millimeters at highest speed. The device will be moving on the on right or left side of scalp patches till uniform pinpoint bleedings will be occurred on these patches. Topical eye drop latanoprost 0.005% (lataprost: Sina daroo, Tehran, Iran) will be applied on these patches by a strile swap twice, immediately before and after performing microneedling. All of these procedures (microneedling combined with latanoprost) will be done every 2 weeks for 3 sessions.

Category

Treatment - Surgery

2

Description

Control side: Under aseptic precaution microneedling is performed by Dr.pen ULTIMA-A6 manufactured in USA. The device is an automated microneedling device, with 12pins cartridge. The depth of penetration will be 2 millimeters at highest speed. The device will be moving on opposite side of scalp patches that side have been received latanoprost combined microneedling till uniform pinpoint bleedings will be occurred on these patches. This procedure (microneedling standalone) will be done every

2 weeks for 3 sessions.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Laser clinic, Imam Reza clinic

Full name of responsible person

Maryam Sadati

Street address

Laser clinic, Imam Reza clinic, Namazi Sq., Shiraz, Iran

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2

Recruitment center

Name of recruitment center

Laser clinic, Shahid Faghihi clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Mahtab. Memarzade

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Research Council, Shiraz University of Medical Sciences, Zand St., Shiraz, Iran

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Grant name

Grant code / Reference number
22872

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
Maryam Sadati

Position
assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Full name of responsible person
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Position

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Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available