

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of efficacy of combined topical Bimatoprost and Fractionated carbon dioxide laser versus Bimatoprost alone in treatment of alopecia areata patients

Protocol summary

Study aim

Determining the effectiveness of topical bimatoprost with fractional carbon dioxide laser in comparison with topical bimatoprost alone in the treatment of patients with alopecia areata

Design

Triple-blind clinical trial, with parallel, randomized groups, for easy randomization using Minitab 16 software

Settings and conduct

This study will be performed on alopecia areata patients referred to Afzalipour Hospital in Kerman. Twenty patients with two alopecia patches in scalp will be randomly placed in one carbon dioxide laser with bimatoprost and in the other patch only bimatoprost. Patient, data analyzer, The person evaluating the response to treatment are unaware of the type of treatment.

Participants/Inclusion and exclusion criteria

Alopecia areata patient who has two similar patches on the scalp Alopecia areata patients treated in the last three months are not included in the study pregnant or breastfeeding patient not included in the study The patient with a history of allergy to prostaglandin analogues is not included in the study

Intervention groups

first group : bimatoprost plus co2 fractional laser second group : bimatoprost alone

Main outcome variables

Percentage of recovery based on lesion area according to SALT Score, patient satisfaction based on 7 Point global-assessment scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210715051895N1**

Registration date: **2021-09-21, 1400/06/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-21, 1400/06/30**

Update count: **0**

Registration date

2021-09-21, 1400/06/30

Registrant information

Name

Alireza Safari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3132 8328

Email address

safarialireza111@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of combined topical Bimatoprost and Fractionated carbon dioxide laser versus Bimatoprost alone in treatment of alopecia areata

patients

Public title

Evaluation of efficacy of combined topical Bimatoprost and Fractionated carbon dioxide laser versus Bimatoprost alone in treatment of alopecia areata

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Alopecia areata patients who have two similar alopecia patches on the scalp

Exclusion criteria:

pregnancy lactation history of allergy to prostaglandin analogue Taking medication or treatment for the past three months that affects the hair cycle Uncontrolled systemic disease Non-patchy alopecia areata and involving area other than the scalp photosensitivity

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

More than 1 sample in each individual

Number of samples in each individual: **2**

Two similar alopecia patches in each individual, one treated with fractional carbon dioxide laser with topical bimatoprost and the other patch treated only with topical bimatoprost

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done using the random number table method. The table consists of numbers from one to one hundred and without a specific pattern or order and is made completely randomly. Then the numbers are touched randomly with their eyes closed. If the number is even, the treatment with bimatoprost is performed alone and if the number is odd, the combined treatment of carbon dioxide laser with bimatoprost is performed.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Ebne Sina Ave; Tahmasb Abad Blvd.

City

Kerman

Province

Kerman

Postal code

761614111

Approval date

2021-05-30, 1400/03/09

Ethics committee reference number

IR.KMU.REC.1400.112

Health conditions studied

1

Description of health condition studied

Alopecia areata

ICD-10 code

L63

ICD-10 code description

Alopecia areata

Primary outcomes

1

Description

Alopecia patch area

Timepoint

at base line ,4,8,12,24 weeks later

Method of measurement

Measurement of hair regrowth rate by physical examination based on Salt score scale

2

Description

Patient satisfaction

Timepoint

4,8,12,24 weeks later

Method of measurement

By 7point global-assessment patient satisfaction questionnaire

Secondary outcomes

1

Description

Erythema

Timepoint

4,8,12 Weeks from the beginning of treatment

Method of measurement

By clinical examination and classification of severity of

complications into mild, moderate and severe

2

Description

Scaling

Timepoint

4,8,12 Weeks from the beginning of treatment

Method of measurement

By clinical examination and classification of severity of complications into mild, moderate and severe

3

Description

skin dryness

Timepoint

4,8,12 Weeks from the beginning of treatment

Method of measurement

By clinical examination and classification of severity of complications into mild, moderate and severe

4

Description

Pruritis

Timepoint

4,8,12 Weeks from the beginning of treatment

Method of measurement

By clinical examination and classification of severity of complications into mild, moderate and severe

Intervention groups

1

Description

Intervention group: Combination therapy with CO2 laser and topical bimatoprost.03%. How to use: Fractional CO2 laser treatment is performed once every two weeks for three months and immediately after the laser and also between laser sessions, the patient will use 0.03% topical bimatoprost twice a day. For CO2 laser, local anesthesia (EMLA cream) is performed with a closed dressing for one hour before the laser and then the desired area is sterilized with 70 ° alcohol and a fractional CO2 laser with the following settings is used: DEKA;Italy;fractional scanning mode;one pulse;spot size=15mm;power=5w;dwel time=500ms;smart stack=3;spacing=700microm;density8.7%;fluence=4.68j /cm2;energy=51.6mj . The patient will receive topical bimatoprost .03% (EXCILIA .03% 3ml sterile solution, IRAN, INOCLON) twice a day, with a cotton applicator in the area of alopecia patch for three months.

Category

Treatment - Drugs

2

Description

Control group: The patient will receive topical bimatoprost .03% (EXCILIA .03% 3ml sterile solution, IRAN, INOCLON) twice a day, with a cotton applicator in

the area of alopecia patch for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Simin Shamsi Meymandi

Street address

Afzalipour Hospital ,Imam khomeyni Ave; Kerman

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meymandi_s@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Ebnesima Ave; Jihad Blvd

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Kerman

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Kerman

Postal code

7619813159

Phone

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abpardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Simin Shamsimeymandi

Position

Professor of dermatology

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Simin Shamsimeymandi

Position

Professor of dermatology

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Other areas of specialty/work

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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

Not applicable

Title and more details about the data/document

Primary and secondary outcome information is available

When the data will become available and for how long

long

Access starts five years after the results are published

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

After reviewing and approving the application by the researchers of this study, information will be available

From where data/document is obtainable

E-mail Alireza Safari safarialireza111@gmail.com

What processes are involved for a request to access data/document

Examination of the application by the study researchers will be a maximum of two months process

Comments