Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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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 analouge 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 photosensivity
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;dwell 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
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Afzalipour Hospital ,Imam khomeyni Ave; Kerman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhty
Street address
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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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Full name of responsible person

Simin Shamsimeymandi

Position

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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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Latest degree

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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

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