

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparative efficacy of fractional CO2 laser and topical clobetasole versus topical clobetasole in treatment of patients with alopecia areata

Protocol summary

Summary

This is a pilot study that will be performed on adult patients with alopecia areata (ophiasis type) referred to Skin Diseases and Leishmaniasis Research Center and clinics of Skin and Stem cell Research Center of Tehran University of Medical Sciences. Inclusion Criteria: Adult patients above 15 years old that do not willing to inject corticosteroid. Ten patients that are eligible will be taken consent form. First, patients will be used ice pack for 10 minutes to anesthetize the treatment site. A half of treatment site in any patient will be used 0.05% clobetasole lotion 2 times a day until complete improvement or 12 weeks and another half will be treated with fractional CO2 laser (Dosis company) with power: 15, Pixel pitch: 1, Dot cycle: 3 and 1 pass every 2 weeks for 4-6 times and then use of the topical clobetasole lotion 2 times a day until complete improvement or 12 weeks. Patients will be followed up every month and hair re-growth rate will be assessed by Point semiquantitative scoring (RGS-5) and trichoscan device according follow: 0- hair re-growth less than 10% 1- hair re-growth 11-25% 2-hair re-growth 26-50% 3- hair re-growth 51-75% 4-hair re-growth more than 75%. Also photography will be taken before and every 2 weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201309041159N11**

Registration date: **2013-10-20, 1392/07/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-10-20, 1392/07/28

Registrant information

Name

Mohamad Ali Nilforoushzadeh

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2220 5158

Email address

sdllrc@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2012-08-18, 1391/05/28

Expected recruitment end date

2013-12-19, 1392/09/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative efficacy of fractional CO2 laser and topical clobetasole versus topical clobetasole in treatment of patients with alopecia areata

Public title

Comparative efficacy of fractional laser and clobetasole in Alopecia areata

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria:1- Severity of alopecia less than of head

2- No sensitivity to corticosteroid 3- No bacterial infection on treatment site 4- No pregnancy or breast-feeding 5- Adult patients above 15 years old that do not willing to inject corticosteroid. Exclusion Criteria: Patients who will not return for follow up visits or are not willing to participate will be excluded.

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

N/A

Randomization description

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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Enghelab Street, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-08-18, 1391/05/28

Ethics committee reference number

62847

Health conditions studied

1

Description of health condition studied

Alopecia areata (ophiasis)

ICD-10 code

L63.2

ICD-10 code description

Ophiasis alopecia areata

Primary outcomes

1

Description

Hair re-growth rate

Timepoint

Before intervention and every month after intervention until 3 months

Method of measurement

Point semiquantitative scoring (RGS-5) and Trichoscan device

Secondary outcomes

empty

Intervention groups

1

Description

A half of treatment site will be used 0.05% clobetasole lotion (Darou pakhsh company) 2 times a day until complete improvement or 12 weeks

Category

Treatment - Drugs

2

Description

Another half of treatment site will be treated with fractional co2 laser (Dosis company) with power: 15, Pixel pitch: 1, Dot cycle: 3 and 1 pass, every 2 weeks for 4-6 times and then use of topical 0.05% clobetasole lotion (Darou pakhsh company) 2 times a day until complete improvement or 12 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Skin and Stem cell Research Center of Tehran University of Medical Sciences

Full name of responsible person

Elaheh Haftbaradaran

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Vice chancellor for research, Tehran University of Medical Sciences, Enghelab Street, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Skin Diseases and Leishmaniasis Research Center, Isfahan University of Medical Sciences, Isfahan, Ir

Full name of responsible person

Elaheh Haftbaradaran

Position

General Physician

Other areas of specialty/work**Street address**

Skin Diseases and Leishmaniasis Research Center, Isfahan University of Medical Sciences, Sedigheh Tahereh (AS) Research Centers Complex, Khorram Ave., Isfahan, Iran

City

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

Skin Diseases and Leishmaniasis Research Center, Isfahan University of Medical Sciences, Isfahan, Ir

Full name of responsible person

Fariba Jaffary

Position

Associate professor

Other areas of specialty/work**Street address**

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City

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jaffary@pharm.mui.ac.ir

Web page address**Person responsible for updating data****Contact****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty