

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Effectiveness comparison of topical 5 fluorouracil and clobetasole combined treatment with/without laser Erbium YAG in vitiligo patients referring to Isfahan educational clinics

Protocol summary

Summary

Objectives: To compare the efficacy of Erbium YAG laser plus cream 5 Fluorouracil and cream clobetasole with cream 5 Fluorouracil and cream clobetasole alone for treatment of vitiligo. Major Inclusion and Exclusion criteria: Inclusion criteria: vitiligo patients with at least two patches on their trunk and extremities excepting periungual areas or genitalia with no perifollicular pigmentation or depigmented hair Exclusion Criteria: patients with poor compliance ; pregnancy; lactation; hepatic or hematologic or renal diseases ; simultaneous application of other therapies. Setting and Conduct: 37 patients having at least two vitiligo patches were selected . after obtaining their consents ,in a dermatology clinic setting, two treatment methods are randomly allocated to the two lesions in each patient: one lesion is treated with cream clobetasole 0.05% and cream 5fluorouracil 5% once every other day for two months, and the other , with one session of laser Erbium YAG (with spot size 2-4 mm and energy 200-500 joules) until the pin point bleeding establishment (usually 3 passes). Immediately after lasering , cream 5 Fluorouracil 5% is applied to the lesion for 2 days . The cream clobetasole 0.05% every other day - 2 months treatment is then conducted. At the end of month two , the conditions of the lesions size, pigmentation scores and complications are assessed and two groups are compared . 2 months after treatment completion accordingly, the patients are revisited for pigmentation score and lesion size. SPSS statistical tests are used to obtain the research objectives.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090229647N1**

Registration date: **2016-09-17, 1395/06/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-17, 1395/06/27

Registrant information

Name

Anis Bostakian

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-11-21, 1394/08/30

Expected recruitment end date

2016-09-20, 1395/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness comparison of topical 5 fluorouracil and clobetasole combined treatment with/without laser

Erbium YAG in vitiligo patients referring to Isfahan educational clinics

Public title

The effect of laser and cream 5 fluorouracil 5% in treatment of vitiligo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion/exclusion criteria: Inclusion criteria: Age ≥ 15 years; patient suffering from vitiligo with at least 2 patch on limbs or trunk(except periungual areas and genitalia); no follicular pigmentation and depigmented hair on lesion Exclusion Criteria: Incidence of drug adverse effects; patients with poor compliance for visit and follow up; pregnancy and lactation; patients with hepatic or hematologic or renal disease; simultaneous application of other therapies .

Age

From **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Isfahan University of Medical Sciences

Street address

Deputy of research of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan.

City

Isfahan

Postal code

Approval date

2016-02-06, 1394/11/17

Ethics committee reference number

IR.mul.REC.1394.3.875

Health conditions studied

1

Description of health condition studied

vitiligo

ICD-10 code

L80

ICD-10 code description

vitiligo

Primary outcomes

1

Description

Vitiligo lesion size change and pigmentation score

Timepoint

2 months and then 4 months after treatment start

Method of measurement

by pictzar software and pigmentation score for vitiligo by an independent dermatologists blinded to the randomization

Secondary outcomes

1

Description

Pain, burning, Pruritis; atrophy, telangiectasia, acne, scar, swelling, tenderness, infection

Timepoint

Two days, one week, two months and four months after treatment start

Method of measurement

Visit, history and physical examination

Intervention groups

1

Description

One of the lesion is randomly treated using one session of Erbium YAG laser(with spot size 2-4 mm and energy 200-500 joules)until the pinpoint bleeding establishment (usually 3 passes) . Immediately after lasering , cream 5 Fluorouracil 5% is applied to the treated region once a day for only two days and cream clobetasole 0.05% is then applied once every other day for two months.

Category

Treatment - Devices

2

Description

In the other lesion, cream 5 Fluorouracil 5% and cream clobetasole 0.05% are applied once every other day for two months with no laser therapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Al Zahra Hospital

Full name of responsible person

Dr Anis Bostakian

Street address**City**

Isfahan

2

Recruitment center

Name of recruitment center

Noor and Hazrat-e-Ali Asghar Hospital

Full name of responsible person

Dr Anis Bostakian

Street address**City**

Isfahan

3

Recruitment center

Name of recruitment center

Sedighe tahere center

Full name of responsible person

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Street address**City**

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of research of Isfahan University of Medical Sciences

Full name of responsible person

Dr Mehdi Nemat bakhsh

Street address

Deputy of research of Isfahan University of Medical Sciences, Hezar jerib Avenue, Isfahan.

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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

Deputy of research of Isfahan 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**

Isfahan university of medical science

Full name of responsible person

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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