

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3668 0048

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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  $\geq 15$  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**

Dr Anis Bostakian

**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.

**City**

Isfahan

**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**

Anis Bostakian

**Position**

resident of dermatology

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## Person responsible for scientific inquiries

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Isfahan university of medical science \_ Skin disease and Leishmaniasis Research Center, Isfah

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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*