

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison between the efficacy of NBUVB phototherapy with or without needling and intralesional synacthen (tetracosactide) in the treatment of patients with refractory lesions of vitiligo

#### Protocol summary

##### Study aim

Determination of efficacy of NBUVB phototherapy with or without needling and intralesional synacthen (tetracosactide) in the treatment of patients with refractory lesions of vitiligo

##### Design

clinical trial with control group, Community based, Prospective study, randomized

##### Settings and conduct

This is a randomized clinical trial that was conducted in 1397 and 1398 on patients referred to the Al-Zahra Hospital and Espasadana Laser Center in Isfahan. In this study, a number of patients with refractory vitiligo who were referred to the Al-Zahra and Espadana Laser Center for NBUVB were selected randomly and after receiving consent to participate in the study, a group of patients undergoing treatment With NBUVB and the other group treated with NBUVB and needling with intalesional cynacthen once a week for three months and then grade of repigmentation evaluated in two groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-Patients with refractory vilitigo with less than 50% skin lesion 2-patches with dimensions of 1-8 cm in two-sided form 3-inactivity of disease during 6 last months exclusion criteria: 1-segmental vitiligo 2-activity of disease during 6 last months

##### Intervention groups

In this study, two groups of 34 patients are be studied. First group are being treated with photo therapy and the other one are being treated with photo therapy and needling with intralesional cynacthen.

##### Main outcome variables

A new way to treat vitiligo with the least side effects and high effectiveness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190515043600N1**

Registration date: **2019-05-23, 1398/03/02**

Registration timing: **retrospective**

Last update: **2019-05-23, 1398/03/02**

Update count: **0**

##### Registration date

2019-05-23, 1398/03/02

##### Registrant information

##### Name

Hossein Farmani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 5222 0849

##### Email address

farmanihossein@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-03-21, 1397/01/01

##### Expected recruitment end date

2019-05-22, 1398/03/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison between the efficacy of NB-UVB phototherapy with or without needling and intralesional synacthen (tetracosactide) in the treatment of patients with refractory lesions of vitiligo

## Public title

Effect of Needling with intralesional synacthen injection in treatment of vitiligo

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

patients with refractory vitiligo with less than 50% skin lesion patches in the size of 1-8 cm in two-sided form  
Inactivity of disease during the last 6 months

### Exclusion criteria:

Segmental vitiligo  
Activity of vitiligo in the last 6 months

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant

## Sample size

Target sample size: 78

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, two groups of 34 people are studied. After getting informed consent from the patient, treatment begins and patient's treatment process is evaluated.

## Placebo

Not used

## Assignment

Crossover

## 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

Isfahan University of medical science, Hezarjarib Ave

##### City

Isfahan

##### Province

Isfahan

## Postal code

8114673461

## Approval date

2019-05-05, 1398/02/15

## Ethics committee reference number

IR.MUI.MED.REC.1398.073

## Health conditions studied

### 1

#### Description of health condition studied

vitiligo

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Grade of Repigmentation

#### Timepoint

At the beginning of the study and three months later

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

### 1

#### Description

Vitiligo skin lesions

#### Timepoint

ابتدای مطالعه و 3 ماه بعد

#### Method of measurement

Percentage

## Intervention groups

### 1

#### Description

Intervention group: NB-UVB Photo therapy and Needling with Intralesional Synacthen Injection

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

مرکز جراحی پلاستیک و لیزر اسپادانا

##### Full name of responsible person

دکتر علی اصیلان

##### Street address

Golshan Alley, Mohtasham Kashani Ave, Hakim Nezami Ave

##### City

Isfahan  
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8175979653  
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+98 31 3625 6981  
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info@spadanalaser.ir  
**Web page address**  
http://www.spadanalaser.ir/

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
دکتر شقایق حق جوی جوانمرد  
**Street address**  
Isfahan University of Medical Sciences, Hezarjarib Ave  
**City**  
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**Province**  
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8174673461  
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**Email**  
sh\_haghjoo@med.mui.ac.ir  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Esfahan 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**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
حسین فرمانی  
**Position**  
Intern  
**Latest degree**

A Level or less  
**Other areas of specialty/work**  
medical student  
**Street address**  
Kowsar dormitory, yakhchal alley, Keshavarzi Ave,  
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8174884841  
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farmanihosseini@yahoo.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr Ali Asilian  
**Position**  
Professor  
**Latest degree**  
Subspecialist  
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Dermatology  
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## Person responsible for updating data

#### Contact

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Esfahan University of Medical Sciences  
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Intern  
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medical student  
**Street address**  
Kowsar Dormitory, Yakhchal Alley, Keshavarzi Ave,  
Keshavarz Bld  
**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174884841

**Phone**

+98 11 5222 0849

**Email**

farmanihosseini@yahoo.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

The data includes patient information and treatment trends and photographs during treatment.

**When the data will become available and for how long**

1year after article publishing

**To whom data/document is available**

Academic researchers

**Under which criteria data/document could be used**

Research

**From where data/document is obtainable**

Email: farmanihosseini@yahoo.com

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

The coordination will be done during correspondence.

**Comments**