

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of Psoralen-narrowband UVB and narrowband UVB in treating Vitiligo

#### Protocol summary

##### Summary

This study aims to evaluate the effects of P-NB UVB and NB-UVB radiations in treating Generalized Vitiligo. In this study 60 patients with Generalized vitiligo who have between 5 to 60 percent body skin involvement are enrolled. Patients are requested to fill out consent forms. Then using a computer software, patients are respectively divided into 2 groups by random. Patients of Group A and group B are placed under P-NB UVB and NB UVB phototherapy treatment. Patients of group A, two hours before each phototherapy session, receive 8-Metoxi Psoralen tablet with 0.6 mg/kg dose. Patients in both groups then have 3 phototherapy sessions in non-consecutive days each week. The initial UVB dose in both groups is 0.25 J/cm<sup>2</sup> and if tolerated, it will be increased by 20 percent each session. Increasing or not increasing the UVB dose depends on the maximum erythema observed in previous session. Patients are recommended to protect their eyes and cover the genital area with enough clothing. Patients are also requested to be under minimum sun exposure. The treatment is ended in the events of 1: approximate or total disappearance of Vitiligo 2: no improvement after 32 sessions or very slow improving process 3: intolerance against treatment due to local or systemic side effects. All patients, before starting treatment and after each 20 sessions are evaluated with photos taken of them (using a camera in the same place and light exposure). The extent of lesion is measured in each evaluation and depigmentation grading is also done. The main results of this study is investigating the efficiency of P-NB UVB in treating vitiligo.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017052816955N6**

Registration date: **2017-06-08, 1396/03/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-06-08, 1396/03/18

##### Registrant information

###### Name

Pouran Layegh

###### Name of organization / entity

department of dermatology, Ghaem hospital, Mashhad, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1801 2861

###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Mashhad University of Medical Sciences

##### Expected recruitment start date

2015-08-23, 1394/06/01

##### Expected recruitment end date

2017-03-19, 1395/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of Psoralen-narrowband UVB and narrowband UVB in treating Vitiligo

##### Public title

Comparison of two photo therapy methods in treating Vitiligo

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: patients with generalized Vitiligo who have 5 to 60 percent body involvement; filling out consent form by patient; age over 13 years old Exclusion criteria: patients who have been under phototherapy or photochemotherapy during 3 months before study starts; patients who have had over 100 phototherapy or photochemotherapy sessions before; pregnancy or breast feeding; heart, kidney and liver disease; children under 13 years old; history of photosensitivity or any dermatosis created by UV light like Lupus Erythematosus; history of previous skin malignancy; history of cataract

### **Age**

From **13 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

Randomized

### **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 Mashhad University of Medical Sciences

##### **Street address**

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street

##### **City**

Mashhad

##### **Postal code**

#### **Approval date**

2015-07-22, 1394/04/31

#### **Ethics committee reference number**

IR.MUMS.fm.REC.1394.212

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Generalized vitiligo

#### **ICD-10 code**

L80

#### **ICD-10 code description**

Vitiligo

## **Primary outcomes**

### 1

#### **Description**

Extent of lesion

#### **Timepoint**

Before starting treatment and after each 20 sessions

#### **Method of measurement**

Taking photos and measuring in hand unit and each hand unit is equal to 1 percent

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Photo therapy using NB-UVB with initial dose of 0.25 J/cm<sup>2</sup> three sessions in a week plus 8-Metoxi Pesoralen with dose of 0.6mg/kg two hours before photo therapy.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Photo therapy using 0.6mg/kg with initial dose of 0.25 J/cm<sup>2</sup> three sessions in a week

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Ghaem Hospital

##### **Full name of responsible person**

Dr Zahra Ashrafi

##### **Street address**

Ghaem Hospital Ahmad Abad Avenue

##### **City**

Mashhad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

**City**

Mashhad

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Zahra Ashrafi

**Position**

Dermatology Assistant

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Poursan Layegh

**Position**

Professor of dermatology

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

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**Position**

Professor of Dermatology

**Other areas of specialty/work**

**Street address**

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**Email**

**Web page address**

## 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*