

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/cm² 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

momenzadeha1@mums.ac.ir

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/cm² 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/cm² 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

Street address

Ghaem Hospital, Ahmad Abad Avenue

City

Mashhad

Postal code

Phone

+98 51 3801 2493

Fax

Email

src@mums.ac.ir

Web page address

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

Other areas of specialty/work

Street address

Ghaem Hospital, Ahmad Abad Avenue

City

Mashhad

Postal code

Phone

+98 51 3801 2861

Fax

Email

layeghpo@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Poursan Layegh

Position

Professor of Dermatology

Other areas of specialty/work

Street address

Ghaem Hospital, Ahmad Abad Avenue

City

Mashhad

Postal code

Phone

Fax

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