# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Jul 2026

## Comparison of effect of NB-UVB with and without topical Latanoprost solution or placebo in Vitiligo Patients: a triple-blind clinical trial study

## Protocol summary

**Study aim**
To compare the effect of NB-UVB with and without topical Latanoprost solution or placebo in Vitiligo Patients

**Design**
This is a triple-blind randomized clinical trial, phase II, in which 30 eligible patients will be randomly assigned to the intervention and control groups

**Settings and conduct**
The eligible patients with Vitiligo who will refer to Sina Hospital in Hamadan City during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be triple-blinded so that neither patients nor the physician who will examine the patients and data analyzer will be aware of the intervention.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Age of 12 to 70 years Vitiligo lesions with at least one lesions on each side Involving at least 20% of the body surface Exclusion criteria: Malignant skin disease Failure of the previous radiotherapy Pregnancy or breastfeeding Hepatic or renal disease Lupus Erythematosus Photosensitivity

**Intervention groups**
Intervention group: NB-UVB radiation at a dose of 0.3 J/cm2 (wavelength from 311 to 313 nm) for a maximum of 3 minutes three times a week for three consecutive months with a Latanoprost solution 0.005% twice a day for three consecutive months Control group: NB-UVB radiation at a dose of 0.3 J/cm2 (wavelength from 311 to 313 nm) for a maximum of 3 minutes three times a week for three consecutive months with a normal saline solution twice a day for three consecutive months

**Main outcome variables**
Improvement of Vitiligo lesions

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20120215009014N283**
Registration date: **2019-05-29, 1398/03/08**
Registration timing: **prospective**

Last update: **2019-05-29, 1398/03/08**
Update count: **0**

**Registration date**
2019-05-29, 1398/03/08

**Registrant information**

**Name**
Jalal Poorolajal

**Name of organization / entity**
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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+98 81 1838 0090

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2019-06-22, 1398/04/01

**Expected recruitment end date**
2019-12-22, 1398/10/01

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Comparison of effect of NB-UVB with and without topical Latanoprost solution or placebo in Vitiligo Patients: a

triple-blind clinical trial study

**Public title**
Comparison of effect of NB-UVB with and without topical Latanoprost solution or placebo in Vitiligo Patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Age of 12 to 70 years Vitiligo lesions with at least one lesions on each sides Involving at least 20% of the body surface
**Exclusion criteria:**
Malignant skin disease Failure of previous radiotherapy Pregnancy or breastfeeding Hepatic or renal disease Lupus Erythematosus Photosensitivity
**Age**
From **12 years** old to **70 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **30**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Random assignment of the right and left sides of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "right" on one sheet and "left" on another. Then, by referring every patient, one of the sheets will be randomly taken. According to whether the sheet is taken right or left is assigned to the intervention group and the other side to the control group.
**Blinding (investigator's opinion)**
Triple blinded
**Blinding description**
The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. The analyzer will be unaware of the type of interventions. Thus, the trial will be run as triple blind.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Hamadan University of Medical Sciences
**Street address**
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
**City**
Hamadan
**Province**
Hamadan
**Postal code**
6517838695
**Approval date**
2018-05-18, 1397/02/28
**Ethics committee reference number**
IR.UMSHA.REC.1398.165

## Health conditions studied

**1**

**Description of health condition studied**
Vitiligo
**ICD-10 code**
L80
**ICD-10 code description**
Vitiligo

## Primary outcomes

**1**

**Description**
Improvement of Vitiligo lesions
**Timepoint**
3 months after the intervention
**Method of measurement**
With physical examination

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: NB-UVB radiation at a dose of 0.3 J/cm2 (wavelength from 311 to 313 nm) for a maximum of 3 minutes three times a week for three consecutive months with a Latanoprost solution 0.005% twice a day for three consecutive months
**Category**
Treatment - Drugs

**2**

**Description**
Control group: NB-UVB radiation at a dose of 0.3 J/cm2 (wavelength from 311 to 313 nm) for a maximum of 3 minutes three times a week for three consecutive months with a normal saline solution twice a day for three consecutive months

**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Sina Hospital in Hamadan City

**Full name of responsible person**
Dr Hanieh Karimi

**Street address**
Sina Hospital, Mirzadeh Eshghi Ave.

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haniehkarimi67@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Hamedan University of Medical Sciences

**Full name of responsible person**
Dr Saeid Bashirian

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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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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**
Hamedan 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**
Hamedan University of Medical Sciences

**Full name of responsible person**
Dr Hanieh Karimi

**Position**
Resident of Dermatology

**Latest degree**
Medical doctor

**Other areas of specialty/work**
Dermatology

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## Person responsible for scientific inquiries

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**Position**
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## Person responsible for updating data

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Dr Jalal Poorolajal

**Position**
Professor of Epidemiology

**Latest degree**
Ph.D.

**Other areas of specialty/work**
Epidemiology

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be 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