

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of topical piperine combined with narrow band UVB on vitiligo treatment: A clinical trial study

#### Protocol summary

##### Summary

**Objectives:** To compare the effect of topical piperine combined with narrow band UVB on vitiligo treatment with narrow band UVB alone. **Design:** Double-blind randomized clinical trial **Setting and conduct:** In this double-blind randomized clinical trial, patients with vitiligo in the facial region referring to Loghman Hakim and Shohada-e-Tajrish hospitals during 2014 to 2016 were invited for participation. Included subjects will be randomly assigned to the two treatment and placebo groups. **Participants:** Inclusion criteria included patients with facial vitiligo. The exclusion criteria were as follows: a history of an autoimmune disease such as alopecia areata, diabetes, Addison's disease, pernicious anemia, Graves' disease, Hashimoto's thyroiditis, systemic lupus erythematosus, and a history of treatment with NB-UVB in the last two weeks, or a history of the use of topical medications for at least 2 weeks prior to the study. Accordingly, a total of 63 patients were selected as the sample population for this study and randomly assigned to two groups of placebo (28 subjects) and piperine (35 subjects). **Intervention:** The case and control groups participated in this study will be treated by topical piperine and placebo respectively for three months. It is worth noting that the standard phototherapy treatment (NB-UVB) will be given in both groups during this time. Piperine solution (1%) will be prepared by dissolving the piperine (with 95% purity, provided from Bioprex Co., India) in a solvent mixture [dimethyl sulfoxide (DMSO): isopropyl alcohol and glycerol] (20: 80). Patients in both groups will undergo NB-UVB phototherapy by Waldman UV 7001 German device for three months, every other day. The energy of the device will be set on 0.05 Joules at the first session and 0.05 Joules will be added to each session to attain a maximum level of 2 Joules and then this energy will be kept constant for further procedure. **Main outcome measure:** The level of repigmentation scored on a scale of 0 to 100 by the subjects along with two blinded dermatologists will be the main outcome

measure. Score 0 means full depigmentation, and 100 is equal to normal skin. Evaluations will be conducted at one, two and three months.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016061527802N2**

Registration date: **2017-07-03, 1396/04/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-07-03, 1396/04/12

##### Registrant information

##### Name

Anoosh Shafiee

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8807 2043

##### Email address

anooshshafiee@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor of research, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2016-06-20, 1395/03/31

##### Expected recruitment end date

2016-09-22, 1395/07/01

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of topical piperine combined with narrow band UVB on vitiligo treatment: A clinical trial study

**Public title**  
Combination therapy in vitiligo

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
Inclusion criteria: diagnosis of facial vitiligo Exclusion criteria: history of alopecia areata; diabetes; Addison's disease; pernicious anemia; Graves disease; Hashimoto's thyroiditis; systemic lupus erythematosus; history of treatment with NB-UVB in the past two weeks; history of applying topical medications in the past 2 weeks prior to the study

**Age**  
No age limit

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **30**

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

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

1

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of dermatology research center, Shohada-E Tajrish Hospital  
**Street address**  
Dermatology research center, Shohada-E Tajrish Hospital, Tajrish Square, Tehran  
**City**  
Tehran  
**Postal code**

**Approval date**  
2010-08-20, 1389/05/29  
**Ethics committee reference number**  
94/192

## Health conditions studied

1

**Description of health condition studied**

Vitiligo  
**ICD-10 code**  
L80

**ICD-10 code description**  
Vitiligo

## Primary outcomes

1

**Description**  
Repigmentation

**Timepoint**  
Every month

**Method of measurement**  
Objective evaluation by two blinded Dermatologists

## Secondary outcomes

1

**Description**  
Patients satisfaction

**Timepoint**  
After four months

**Method of measurement**  
Objective score given by the patient on a scale of 0-10

2

**Description**  
Side effects of the treatment

**Timepoint**  
Every month

**Method of measurement**  
History taking and physical examination

## Intervention groups

1

**Description**  
Treatment with NBUVB plus a topical ointment as the placebo  
**Category**  
Placebo

2

**Description**  
Treatment with NBUVB plus local application of Piperine

solition  
**Category**  
Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Dermatology Clinic of Shohada-E Tajrish hospital  
**Full name of responsible person**  
Anoosh Shafiee  
**Street address**  
Tajrish Square  
**City**  
Tehran

2

### Recruitment center

**Name of recruitment center**  
Dermatology Clinic of Loghman Hakim hospital  
**Full name of responsible person**  
Anoosh Shafiee  
**Street address**  
Dermatology Ward, Loghman Hakim Hospital, South Kargar St., Makhsos Crossroad  
**City**  
Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Vice Chancellor of Research, Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Seyed Ali Ziai  
**Street address**  
3rd Floor, Faculty of Medicine, Evin, Shahid Chamran Highway  
**City**  
Tehran  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Vice Chancellor of Research, Shahid Beheshti 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**  
Loghman Hakim Hospital, Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Anoosh Shafiee  
**Position**  
MD, Dermatology resident  
**Other areas of specialty/work**  
**Street address**  
Dermatology Ward, Loghman Hakim Hospital, South Kargar St., Makhsos Crossroad  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 8836 1563  
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**Email**  
anooshshafiee@sbm.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Loghman Hakim Hospital, Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Anoosh Shafiee  
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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Position**

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**Postal code**

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**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*