

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the efficacy of NB-UVB phototherapy with oral N-acetylcysteine compared with NB-UVB phototherapy alone in the treatment of vitiligo patients: a randomized controlled clinical trial

#### Protocol summary

##### Study aim

Determining the effectiveness of NB-UVB phototherapy combined with oral N-acetylcysteine (NAC) in comparison with NB-UVB phototherapy alone in the treatment of vitiligo

##### Design

A randomized clinical trial with a control group, parallel groups, single-blind, phase 3 on 40 patients, randomization is performed through a table of random numbers.

##### Settings and conduct

This study will be performed on 40 patients in Rasoul Akram Hospital in a four-month treatment period. Patients will be divided into two groups of 20: one group of oral NAC with NB-UVB phototherapy and the other group with NB phototherapy. -They will receive the UVB alone as a control group. This blind study is conducted by a researcher and analyzer and sealed envelopes are used for concealment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: People with generalized vitiligo.  
Exclusion criteria: Patients with focal or segmental vitiligo, patients with other skin or systemic diseases, history of peptic ulcer, photosensitivity, patients who have received systemic or topical medication for two months.

##### Intervention groups

Patients enter the intervention in two groups of 20 people, one group will receive oral NAC along with NB-UVB phototherapy and the other group will receive NB-UVB phototherapy alone as a control group.

##### Main outcome variables

Vitiligo severity score; patient's satisfaction with the treatment; patient's tolerance of the treatment

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210729052013N1**

Registration date: **2021-12-04, 1400/09/13**

Registration timing: **prospective**

Last update: **2021-12-04, 1400/09/13**

Update count: **0**

##### Registration date

2021-12-04, 1400/09/13

##### Registrant information

##### Name

Saeideh Farahani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2262 3759

##### Email address

farahani.104@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-12-11, 1400/09/20

##### Expected recruitment end date

2022-02-09, 1400/11/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the efficacy of NB-UVB phototherapy with oral N- acetylcysteine compared with NB-UVB phototherapy alone in the treatment of vitiligo patients: a randomized controlled clinical trial

## Public title

Evaluation of the efficacy of oral N- acetylcysteine in the treatment of vitiligo patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

People with generalized vitiligo who volunteer for NB-UVB phototherapy

### Exclusion criteria:

Patients with focal or segmental vitiligo Patients with other skin diseases Patients with a history of gastrointestinal ulcers Patients with photosensitivity Patients who have received systemic or topical medication for 2 months Pregnant and lactating women

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

- Investigator
- Data analyser

## Sample size

Target sample size: 40

## Randomization (investigator's opinion)

Randomized

## Randomization description

A simple randomization method is used and the tool used is a random number table. Numbers reading is from top to bottom. Even numbers are considered for intervention a and odd numbers for intervention b. Code a will be used for oral acetylcysteine and NB-UVB phototherapy and code b will be used for NB-UVB phototherapy alone. Sealed envelopes will be used for concealment.

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

Participants are invited to study and after obtaining informed consent are divided into intervention and control groups. The lead researcher will study the patients' sampling, recording, and follow-up, and at each visit the second researcher, who is blind, will calculate the Vitiligo Extent Tensity Index (VETI) score, which will be completed by the lead researcher in the questionnaire. Finally, the blind analyzer will perform statistical calculations of this study according to codes a and b.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Iran University of Medical Sciences

##### Street address

No.2, Hadi Mohamad Alley, Atari Moghadam Ave, Khaghani Ave, Shariati Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

1916963568

#### Approval date

2020-10-31, 1399/08/10

#### Ethics committee reference number

IR.IUMS.FMD.REC.1399.703

## Health conditions studied

### 1

#### Description of health condition studied

vitiligo disease

#### ICD-10 code

L80

#### ICD-10 code description

Vitiligo

## Primary outcomes

### 1

#### Description

Vitiligo severity score

#### Timepoint

At the beginning of the study (before the intervention), 2 and 4 months after the start of treatment.

#### Method of measurement

Vitiligo Extent Tensity Index (VETI) score, which its maximum value is 55.5.

## Secondary outcomes

### 1

#### Description

The patient's satisfaction with the treatment

#### Timepoint

Measurement periods: 2 and 4 months after starting treatment.

#### Method of measurement

At each visit, patients determine their level of satisfaction by choosing one of the following options: 1.

No 2. A little 3. Moderate 4. Good 5. Excellent

## 2

### Description

The patient's tolerance of the treatment

### Timepoint

Measurement periods: 2 and 4 months after starting treatment.

### Method of measurement

At each visit, patients determine their tolerance by choosing one of the following options: 1. Yes 2. No

## Intervention groups

### 1

#### Description

intervention group: Participants in the intervention group are treated with Dr Honle Drmalight 3000 phototherapy device with a wavelength of 311 nm 3 times a week for four months. The initial dose for each patient is 65 mj / cm<sup>2</sup> and increases by 65 ml. Joules per square centimeter in each session is adjusted to a dose of 1000 millijoule per square centimeter. In addition to phototherapy, the group received oral N-acetylcysteine tablets (manufactured by Avesina), an antioxidant derived from the amino acid cysteine, at a dose of 600 mg, twice daily, starting two weeks before the start of NB-UVB until the end. 4 months is also received.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Participants in the Control group are treated with Dr Honle Drmalight 3000 phototherapy device with a wavelength of 311 nm 3 times a week for four months. The initial dose for each patient is 65 mj / cm<sup>2</sup> and increases by 65 ml. Joules per square centimeter in each session is adjusted to a dose of 1000 millijoule per square centimeter.

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasoul Akram Hospital

##### Full name of responsible person

Saeideh Farahani

##### Street address

Rasoul Akram Hospital, Niyayesh St, Sattar Khan Ave

##### City

Tehran

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##### Postal code

1445613131

##### Phone

+98 21 4635 1000

##### Email

hrmc@iums.ac.ir

##### Web page address

http://hrmc.iums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Leila Irani

##### Street address

Iran Univercity Of Medical Sciences, Hemat Highway next to Milad Tower

##### City

Tehran

##### Province

Tehran

##### Postal code

1449614535

##### Phone

+98 21 86701

##### Email

admins@iums.ac.ir

##### Web page address

http://iums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Saeideh Farahani

##### Position

Resident

##### Latest degree

Medical doctor

**Other areas of specialty/work**

Dermatology

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**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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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