

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)

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+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

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Province

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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 / cm² 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 / cm² 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Leila Irani

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

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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

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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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