

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of vitamin C supplementation on oxidative stress indices and skin repigmentation of patient with vitiligo

#### Protocol summary

##### Study aim

Determining the effect of vitamin C supplementation on serum levels of oxidative stress indicators and skin repigmentation in vitiligo patients

##### Design

Randomized clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 to 3 on 44 patients, RAS software was used for randomization.

##### Settings and conduct

If the patient in the phototherapy clinic of Razi skin hospital in Tehran, has the conditions, first verbal explanations will be given to the patients about the objectives and method of the study. If the patients are willing to cooperate, they will be asked to sign a consent form. Before allocating the study subjects to the intervention and placebo groups, the patients' height, weight, body mass index, and waist circumference will be measured and recorded. Then, an experienced interviewer will collect information related to the individual characteristics of the patients. Then 8 ml of fasting blood samples will be taken from all the subjects for biochemical measurements. Also, vitamin C and placebo tablets in similar packages will be given to patients in two groups in a double-blind manner; And the researcher and the studied people will not know about the type of pills used.

##### Participants/Inclusion and exclusion criteria

Diagnosis of vitiligo was confirmed by a dermatologist Newly diagnosed vitiligo patient and less than the phototherapy session. Adults 20-60 years old Pregnancy, breastfeeding having history of malignancy, kidney stones, other chronic and inflammatory diseases except vitiligo Taking antibiotics, antivirals and antifungals Use of vitamin C supplements and antioxidants in the last 3 months Any history of alcohol and tobacco use

##### Intervention groups

Vitamin C, Placebo

##### Main outcome variables

Total antioxidant capacity Superoxide dismutase

Glutathione peroxidase Malondialdehyde Total oxidant status

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230123057193N1**

Registration date: **2023-04-17, 1402/01/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-04-17, 1402/01/28**

Update count: **0**

##### Registration date

2023-04-17, 1402/01/28

##### Registrant information

##### Name

Soraiya ebrahimpour-koujan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2232 9521

##### Email address

ebrahimpour\_s@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-08, 1402/01/19

##### Expected recruitment end date

2023-09-21, 1402/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of vitamin C supplementation on oxidative stress indices and skin repigmentation of patient with vitiligo

**Public title**

The effect of vitamin C supplementation on oxidative stress indices and skin repigmentation of patient with vitiligo

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Definitive diagnosis of vitiligo by a dermatologist, without gender restrictions Newly diagnosed vitiligo patient (under one month) or less than 10 phototherapy sessions Adults 20-60 years old

**Exclusion criteria:**

Being pregnant or breastfeeding Underlying diseases, including malignancy, history of kidney stones, other chronic and inflammatory diseases except vitiligo Taking antibiotics, antivirals and antifungals Use of vitamin C supplements and antioxidants in the last 3 months Any history of alcohol and tobacco use

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The study subjects will be block-blocked based on gender and receiving or not receiving phototherapy, and then they will be randomly divided into two intervention groups with vitamin C and placebo. Random allocation: RAS) (size 4) were assigned to intervention and placebo groups, and patients were placed in blocks of 4 based on receiving or not receiving phototherapy and gender. In this study, the participants are randomly placed in two intervention and placebo groups so that researchers can compare different treatments. Researchers and participants cannot arbitrarily play a role in assigning people to groups. Random assignment of people to the intervention or placebo group will be done by an experienced expert.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

All subjects and researchers and healthcare personnel who are responsible for the care of patients will be unaware of the existing grouping until the end of the study; In such a way, the researcher and the person who takes the sample, like the study participants, are unaware of which patient will receive the vitamin pill or the placebo. Patients are also unaware of the type of pill received. Drugs and placebos are coded by a person who is completely unaware of the study process, and this code is placed in an envelope that indicates whether it is a drug or a placebo code. One group will receive drug A and one group will receive drug B. Also, pills containing vitamin C and placebo, which have the same color, smell, and size as the vitamin pill, will be given to the study subjects every 4 weeks by another person who has no knowledge of the research process. Hence, this study will be a double-blind study. Placebo tablets contain starch and are completely similar to vitamin C tablets in terms of color, appearance and smell. Placebo tablets are also prepared by the same company that manufactures vitamin C.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Keshavarz blv., Ghods st.

**City**

Tehran

**Province**

Tehran

**Postal code**

141556117

**Approval date**

2023-01-07, 1401/10/17

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1401.649

**Health conditions studied****1****Description of health condition studied**

Vitiligo

**ICD-10 code**

L80

**ICD-10 code description**

## Primary outcomes

### 1

#### Description

Catalase

#### Timepoint

Baseline and 8 weeks after intervention

#### Method of measurement

ELISA assay

## Secondary outcomes

### 1

#### Description

Regimentation

#### Timepoint

Baseline and 8 weeks after intervention

#### Method of measurement

vitiligo area scoring index (VASI) score

### 2

#### Description

Superoxide dismutase

#### Timepoint

ابتدای مطالعه (قبل از شروع مداخله) و 8 هفته پس از مداخله

#### Method of measurement

ELISA assay

### 3

#### Description

Total oxidant status

#### Timepoint

Baseline and 8 weeks after intervention

#### Method of measurement

ELISA assay

### 4

#### Description

Total antioxidant capacity

#### Timepoint

Baseline and 8 weeks after intervention

#### Method of measurement

ELISA assay

### 5

#### Description

Malondialdehyde

#### Timepoint

Baseline and 8 weeks after intervention

#### Method of measurement

ELISA assay

### 6

#### Description

Glutathione peroxidase

#### Timepoint

Baseline and 8 weeks after intervention

#### Method of measurement

ELISA assay

## Intervention groups

### 1

#### Description

Intervention group will receive daily 1 tablets of vitamin C 1000 mg with water for 8 weeks. Vitamin C tablets will be purchased from the Gol-darou Company with C Fix brand. All the patients will be monitored for consumption of tablets by daily checklists and recall messages

#### Category

Treatment - Drugs

### 2

#### Description

The control group will receive daily 1 tablets of placebo with water for 8 weeks. placebo tablets will be purchased from the Gol-darou Company. All the patients will be monitored for consumption of tablets by daily checklists and recall messages

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Razi hospital

##### Full name of responsible person

Soraiya Ebrahimpor-koujan

##### Street address

st. vahdat eslami

##### City

Tehran

##### Province

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##### Postal code

1199663911

##### Phone

+98 21 5563 0220

##### Email

nutri.seam1@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Research assistant of Tehran University of Medical

Sciences

**Full name of responsible person**

Mahshad Khodarahmaniyan

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nutri.seam1@gmail.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Research assistant of Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Soraiya Ebrahimpour-koujan

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Tehran-Vahdat-Islami Street-Vahdat-Islami Square-Razi Dead End-Razi Skin Specialist Hospital

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## Person responsible for scientific inquiries

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**Position**

Assistant Professor

**Latest degree**

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## Person responsible for updating data

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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