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)

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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

L80- Diseases of the skin and subcutaneous tissue.

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
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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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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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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