

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of Vitamin E and C supplements on improving asthma

Protocol summary

Summary

The purpose of this double blind clinical trial is to determine the effect of vitamin E & C, alone and in combination, on the improvement of asthma. 80 asthmatic patients, referred to Mofateh Special Clinics and Yasuj Imam Sajjad Hospital, will be randomly assigned into one of following groups to receive 400 mg Vitamin E per day, 800 mg vitamin C, 400 mg Vitamin E as well as 800 mg vitamin C, or placebo for 12 weeks. Holms-Rahe questionnaire was used to investigate daily stress. Dietary intake is measured using 24-hour dietary recalls questionnaire and respiratory factors are measured by peak flow meter and Spiro meter. Severity of asthma and the serum levels of vitamin C and E are measured before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904224359N1**

Registration date: **2010-09-13, 1389/06/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-09-13, 1389/06/22

Registrant information

Name

Leila Nikrooz

Name of organization / entity

Yasouj Univercity Medical Siencese

Country

Iran (Islamic Republic of)

Phone

+98 74 1223 4115

Email address

l-nikrooz@yums.ir

Recruitment status

Recruitment complete

Funding source

Yasuj University of Medical Sciences

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-11-22, 1390/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Vitamin E and C supplements on improving asthma

Public title

Effect of Vitamin E and C supplements on improving asthma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: History of at least one year asthma, age 18-50 years Exclusion Criteria: suffering from other diseases other than asthma, smoking, consumption of contraceptive pills

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description
Blinding (investigator's opinion)

Double blinded

Blinding description**Placebo**

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Yasuj University of Medical Sciences

Street address

Imam Sajjad Hospital, Yasuj, Kohgiluyeh and Boyer
Ahmad Province

City

Yasuj

Postal code**Approval date**

2010-03-16, 1388/12/25

Ethics committee reference number

7873/5/23/پ

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

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

Primary outcomes**1****Description**

Asthma severity (severe - moderate - mild)

Timepoint

Before intervention and 6 and 12 weeks after
intervention

Method of measurement

Classification of Asthma Severity: Method of Australian
national Asthma Campaign 1998

Secondary outcomes**1****Description**

Serum levels of vitamins A and C

Timepoint

Before and after intervention

Method of measurement

Serum levels of vitamins A and C

2**Description**

stress

Timepoint

Before and after intervention

Method of measurement

The holms- Rahe stress scale

3**Description**

dietary intake

Timepoint

before and after intervention

Method of measurement

a 24 hours dietary recall

Intervention groups**1****Description**

400 mg of vitamin E, daily, for 12 weeks

Category

Treatment - Drugs

2**Description**

Placebo (starch powder) for 12 weeks

Category

Placebo

3**Description**

800 mg of vitamin C, daily for 12 weeks

Category

Treatment - Drugs

4**Description**

400 mg of Vitamin E plus 800 mg ascorbic acid, daily for
12 weeks

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid Mofatteh Clinic No. 2

Full name of responsible person

Leila Nikrooz, Mr. Posesh, Ms Eftekhari

Street address

Mofatteh Clinic shahid No. 2, Yasuj, Kohgiluyeh and Boyer Ahmad

City

Yasuj

2

Recruitment center

Name of recruitment center

Imam Sajjad Hospital

Full name of responsible person

Street address

City

Yasuj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Mr. Mehdi Akbar Tabar

Street address

Yasuj University of Medical Sciences, Yasuj, Kohgiluyeh and Boyer Ahmad Province

City

Yasuj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasuj 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

Yasuj University of Medical Sciences

Full name of responsible person

Leila Nikrooz

Position

Instructor, School of Nursing and Midwifery

Other areas of specialty/work

Street address

Faculty of Nursing and Midwifery, Yasuj University of

Medical Sciences, Yasuj, Kohgiluyeh and Boyer Ahmad

City

Yasuj

Postal code

Phone

+98 74 1223 3705

Fax

Email

lnikrooz@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Dr Hesamodin Nabavi zadeh

Position

Specialty Asthma and Immunology

Other areas of specialty/work

Street address

Yasuj University of Medical Sciences, Yasuj, Kohgiluyeh and Boyer Ahmad Province

City

Yasuj

Postal code

Phone

+98 91711108767

Fax

Email

drhesamnabavi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Leila Nikrooz

Position

Faculty member, Faculty of Nursing and Midwifery

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

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