

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effects of oral vitamin E on the treatment of atopic dermatitis and comparing with placebo

Protocol summary

Summary

According to the previous studies, cost-benefit of vitamin E and also lack of serious side effects of vitamin E with dosage 400 IU per day, we decided to evaluate the intake of oral vitamin E in the treatment of atopic dermatitis and compare with placebo. This study is a double blind clinical trial which seventy people with atopic dermatitis based on the Hanifin and Rajka's diagnostic criteria randomly selected from educational skin clinics. These seventy people were divided randomly in two groups A and B with thirty five patients. The group A received drug package A and group B received drug package B. Since this study was double blinded, these packages, which contained vitamin E and placebo, were coded to A and B by corporator. Each group took the drug package four months. Extent, severity and subjective symptoms including itch and sleeplessness were measured by scored index every month. In addition every two weeks the patients were followed up by phone to make sure of using drug package and asking about any side effects or exacerbation of disease. Three months after finishing of intervention recurrence rate of atopic dermatitis were evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105016350N1**

Registration date: **2011-05-31, 1390/03/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-05-31, 1390/03/10

Registrant information

Name

Arghavan Mokhtarian

Name of organization / entity

Isfahan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan university of medical sciences

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of oral vitamin E on the treatment of atopic dermatitis and comparing with placebo

Public title

Effects of Vitamin E on the treatment of atopic dermatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All people with atopic dermatitis based on the Hanifin and Rajka's diagnostic criteria in age range of 10-50 years except these: 1-Lactating woman, 2- Pregnant woman, 3- Severe form of a disease with scored index of more than 50, 4-Taking systemic corticosteroid or immunosuppressive drugs, 5-

Coagulopathy, 6- Need to hospitalization, 7- History of allergy to vitamin E. Exclusion criteria: 1- Getting pregnant during the treatment period, 2- Exacerbation of the disease, 3- Allergy symptoms to vitamin E.

Age

From **10 years** old to **50 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice Chancellor for Research, School of Medicine, Isfahan university of medical sciences

Street address

Vice Chancellor of Research Office, School of Medicine, Isfahan University of Medical Sciences

City

Isfahan

Postal code

Approval date

2009-07-26, 1388/05/04

Ethics committee reference number

388213

Health conditions studied

1

Description of health condition studied

Atopic dermatitis

ICD-10 code

L20

ICD-10 code description

Atopic dermatitis

Primary outcomes

1

Description

Sleep

Timepoint

Monthly

Method of measurement

Visual analogue scale 0-10

2

Description

Itch

Timepoint

Monthly

Method of measurement

Visual analogue scale 0-10

3

Description

Extent of lesions

Timepoint

Monthly

Method of measurement

Transparent paper rating based on unit area

Secondary outcomes

1

Description

Gastrointestinal symptoms after taking vitamin E

Timepoint

monthly

Method of measurement

Questionnaire

2

Description

Skin rash or any new skin symptom

Timepoint

monthly

Method of measurement

Questionnaire

Intervention groups

1

Description

intervention group: vitamin E tablet 400 IU/ oral/ /daily/ I /for 4 months

Category

Treatment - Drugs

2

Description

control group: placebo tablet/ oral/daily/ I/ for 4 months
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Skin clinic of Nur hospital
Full name of responsible person
Street address
City
Isfahan

2

Recruitment center

Name of recruitment center
Skin clinic of Alzahra hospital
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellery for research
Full name of responsible person
Dr. Peyman Adibi
Street address
Vice Chancellor of Research Office, School of
Medicine, Isfahan University of Medical Sciences
City
Isfahan

Grant name

Grant code / Reference number

388213

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

Yes

Title of funding source

Vice chancellery for research

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
Isfahan university of medical sciences
Full name of responsible person
Dr.Gita Faghihi
Position
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Other areas of specialty/work
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Person responsible for updating data

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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