

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Oral vitamin E in reducing mucocutaneous side effects of Isotretinoin

Protocol summary

Summary

The purpose of this study was to determine the effects of vitamin E on reduction of mucocutaneous side effects of Isotretinoin in the treatment of acne vulgaris. In this placebo-controlled trial, 80 patients visited in dermatology special clinic were randomly assigned into the intervention or control group to receive 0.5-1 mg/kg/day Isotretinoin as well as 800 IU/day vitamin E or placebo for 6 weeks. The mucocutaneous side effects were clinically evaluated at the end of weeks 1, 4, and 6.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905022085N4**

Registration date: **2010-07-24, 1389/05/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-07-24, 1389/05/02

Registrant information

Name

Neda Parvin

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1333 5652

Email address

nedali285@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2004-09-22, 1383/07/01

Expected recruitment end date

2005-02-19, 1383/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Oral vitamin E in reducing mucocutaneous side effects of Isotretinoin

Public title

Oral vitamin E in reducing mucocutaneous side effects of Isotretinoin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: suffering from Acne vulgaris, indication of treatment with Isotretinoin
Exclusion criteria: age lesser than 15 years old, pregnancy, breast feeding

Age

From **15 years** old to **39 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

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord University of Medical Sciences

Street address

Shahrekord University of Medical Sciences

City

Shahrekord

Postal code

Approval date

1383-06-06, 765/01/-1017

Ethics committee reference number

1-6-83

Health conditions studied

1

Description of health condition studied

acne vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

mucocutaneous side effects of Isotretinoin

Timepoint

After 4 and 6 weeks

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Isotretinoin, 0.5-1 mg/kg/day, as well as 800 IU/day vitamin E for 6 weeks

Category

Treatment - Drugs

2

Description

Isotretinoin, 0.5-1 mg/kg/day, as well as placebo for 6 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Skin Diseases Clinic, Shahrekord University of Medical Sciences

Full name of responsible person

Neda Parvin

Street address

Shahrekord University of Medical Sciences, Rahmatie

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Research deputy

Street address

Shahrekord University of Medical Sciences, Rahmatie, Shahrekord

City

Shahrekord

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahrekord 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahrekord Medical University Of Science

Full name of responsible person

Neda Parvin

Position

Lecturer

Other areas of specialty/work**Street address**

Shahrekord University of Medical Sciences, Rahmatie,
Shahrekord

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np285@yahoo.com

Web page address**Position**

Lecturer

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+98 38 1333 5648

Fax**Email**

np285@yahoo.com

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

Person responsible for updating data

Contact

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person

Neda Parvin