# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 2026

## The efficacy of omega – 3 in treatment of Acne – Vulgaris: a DOUBLE BLIND STUDY

## Protocol summary


**Summary**

We designed this study to evaluate the effect of Ώ-3 on moderate acne-Vulgaris patients' candidate for systemic therapy. Double blind randomized clinical trialson 60 patients in 2 groups (intervention & control) are selected. Patients have indication of systemic therapy based on bloke randomization included. Patients were excluded if had: diabetes mellitus; hypertension; significant pulmonary, hepatic or renal disease; typical angina or myocardial infarction; use of antihypertensive, oral hypoglycemic or lipid lowering agent or anticoagulant drug; glucocorticoids equivalent to greater than 10 mg Prednisolone daily; all pregnant or lactating women. All subjects were asked to stop all vitamin and mineral supplements, including fish oils, at least 6 weeks before commencing the study. The patients in Intervention group were adminitered to take Ώ-3 Capsule (2 capsule daily) in addition to Doxycyclin Capsule (200 mg daily) for a total of 4 weeks. Randomization occurred off-site by an independent body. The Control group was Doxycyclin Capsule (200 mg daily).Each Ώ-3 Capsule contain 1 gram fish oil (180 mg EPA & 120 mg DHA).Patients were assessed at week 4.All clinical assessments were Performed by the same nurse who was blinded to Study medication.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2012080110471N1**
Registration date: **2012-08-31, 1391/06/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2012-08-31, 1391/06/10


**Registrant information**

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Milad Masaeli
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**Recruitment status**

**Recruitment complete**


**Funding source**

Kurdestan University of Medical Science


**Expected recruitment start date**

2010-09-23, 1389/07/01

**Expected recruitment end date**

2012-08-22, 1391/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The efficacy of omega – 3 in treatment of Acne – Vulgaris: a DOUBLE BLIND STUDY

**Public title**

The efficacy of omega – 3 in treatment of Acne – Vulgaris: a DOUBLE BLIND STUDY

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

inclusion criteria: acne- vulgaris patients have indication of systemic therapy treatment exclusion criteria:diabetes mellitus; hypertension ; significant pulmonary, hepatic or renal disease ; typical angina or myocardial infarction;

use of antihypertensive, oral hypoglycemic or lipid lowering agent or anticoagulant drug; glucocorticoids equivalent to greater than 10 mg Prednisolone daily; all pregnant or lactating women.

**Age**
No age limit

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Kurdistan Local Research Ethics Committee

**Street address**
Kurdestan University of Medical Science,Sanandaj,Iran

**City**
Sanandaj

**Postal code**
66177-13446

**Approval date**
2010-07-19, 1389/04/28

**Ethics committee reference number**
49963/پ/14/پ

## 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**
improvment skin lesion such as comedone,papules,pustules,nodules

**Timepoint**
1 month

**Method of measurement**
with count the facial lesion

## Secondary outcomes

### 1

**Description**
improvement skin lesion such as comedone, papules, pustules, nodules

**Timepoint**
1 month

**Method of measurement**
with count the facial lesion

## Intervention groups

### 1

**Description**
The patients in Intervention group were administered to take Ώ-3 Capsule (2 capsule daily) in addition to Doxycyclin Capsule (200 mg daily) plus topical antibactrial (Erythromycin Solution for4%,twice a day) for total of 4 weeks.Each Ώ-3 Capsule contains 1 gram fish oil (180 mg EPA & 120 mg DHA).

**Category**
Treatment - Drugs

### 2

**Description**
For control group was administered Doxycyclin 200 mg daily and topical antibacterial (Erythromycin Solution 4% twice a day) for total 4 weeks.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Clinic of Hair & Dermatology oF Dr.Hassanzadeh

**Full name of responsible person**
Dr.Seyyed Jamal Adin Hassanzadeh

**Street address**
Jina Doctors building,Keshavarz street,Azadi square

**City**
Sananadaj

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Kurdestan University of Medical Science
**Full name of responsible person**
Fardin Gharibi
**Street address**
Kurdestan University of Medical Science, Pasdaran Ave, Azadi Square,
**City**
Sanandaj
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Kurdestan University of Medical Science
**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**
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## Person responsible for scientific inquiries

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Dermatologist,Associative Professor Kurdestan University of Medical Science
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## Person responsible for updating data

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## 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*