Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Ω-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 Ω-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 Ω-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

Name

Milad Masaeli

Name of organization / entity

Kurdistan University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 3356 5240

Email address

drmilmas@muk.ac.ir

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 Ω-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 Ω-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
Name of organization / entity
Kurdestan University of Medical Science
Full name of responsible person
Milad Masaeli
Position
Medical Student
Other areas of specialty/work
Street address
Kurdestan University of Medical Science, Pasdaran Ave, Azadi Square
City
Sanandaj
Postal code
Phone
+98 87 1662 9246
Fax
Email
drmilmas@muk.ac.ir,drmilmas@yahoo.com,drmilmas@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Dermatologist,Associative Professor Kurdestan University of Medical Science
Full name of responsible person
Seyyed Jamal Adin Hassanzadeh
Position
Professor Kurdestan University of Medical Science
Other areas of specialty/work
Street address
Vakil street, Beesat hospital
City
Sanandaj
Postal code
Phone
+98 87 1662 9246
Fax
Email
drmilmas@muk.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Milad Masaeli
Position
Student Research Committee of Kurdestan University of Medical Science
Other areas of specialty/work
Street address
Kurdestan University of Medical Science, Psdaran Ave, Azadi Square
City
Sanandaj
Postal code
Phone
+98 87 1662 9246
Fax
Email
drmilmas@gmail.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