Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of omega-3 versus placebo on acne in patients aged 13-50 years: a triple blinded randomized clinical trial

Protocol summary

Summary

Objectives: To assess the effect of omega-3 on acne. Design: A triple blinded randomized clinical trial. Setting and conduct: All eligible patients with acne vulgaris who will refer to clinic of Farshchian Hospital will be enrolled in to the trial. Inclusion criteria: having moderate to severe facial acne vulgaris. Exclusion criteria: (a) being immunodeficient; (b) contraindication of acne treatment; (c) using medications which have interaction with omega-3. Intervention: Oral doxycycline 100 mg daily plus oral 1000 mg omega-3, daily, for 12 weeks. Control: Oral doxycycline 100 mg daily plus oral placebo including starch, daily, for 12 weeks Primary outcome: The severity of acne at the end of sixth and twelfth weeks based on global acne grading system.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013091714690N1**
Registration date: **2014-02-26, 1392/12/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-02-26, 1392/12/07

Registrant information

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Hamadan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2012-09-22, 1391/07/01

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 versus placebo on acne in patients aged 13-50 years: a triple blinded randomized clinical trial

Public title

The effect of omega-3 versus placebo on acne in patients aged 13-50 years

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having moderate to severe facial acne vulgaris. Exclusion criteria: (a) being immunodeficient; (b) contraindication of acne treatment; (c) using medications which have interaction with omega-3.

Age

From **13 years** old to **50 years** old

Gender

Both

Phase

2

Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomization: 30 envelopes containing the letters A (intervention group) and 30 envelopes containing the letters B (control group) will be numbered from one to 60 based on a table of random numbers. Then, the patients will be assigned to each envelope in order. Blinding: The patients will receive either Omega-3 capsule or placebo (starch) capsule with the same shape but different content. Thus, they will not aware of the intervention. In addition, the examiner, who will assess the results of intervention, and the analyzer of the data will not aware of the type of treatment received by the patients. Thus, the trial will be run as triple blinded.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethic Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor of Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
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6517838695
Approval date
2012-08-18, 1391/05/28
Ethics committee reference number
P/D/16/35/9/1842

Health conditions studied

1

Description of health condition studied
Acne
ICD-10 code
L70
ICD-10 code description
Acne

Primary outcomes

1

Description
The severity of acne
Timepoint
at the end of sixth and twelfth weeks
Method of measurement
based on global acne grading system

Secondary outcomes

empty

Intervention groups

1

Description
Oral doxycycline 100 mg daily plus oral 1000 mg omega-3, daily, for 12 weeks.
Category
Treatment - Drugs

2

Description
Oral doxycycline 100 mg daily plus oral placebo including starch, daily, for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Hospital
Full name of responsible person
Dr Hassan Faghani
Street address
Farshchian Hospital, Mirzadeh Eshghi Ave.
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences
Full name of responsible person
Dr Saeid Bashirian
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Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor for Research the Technology, Hamadan 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

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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