

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Studies on the possible lowering of occupational errors by intervention on inflammatory, oxidative stress factors and depression in Tehran refinery oil shift workers treated with omega 3 and vitamin C.

Protocol summary

Summary

This research to determine the effect of omega-3 and vitamin C in serum cortisol, CRP, TAC, MDA, IL-6 and depression score and the number of job errors in shift workers Tehran oil refinery was designed. This study is a double-blind intervention study with a placebo control group and 2 months of intervention with omega-3 [each capsule containing 180 mg EPA (eicosapentaenoic acid) and 120 mg DHA (docosahexaenoic acid)] and vitamin C (250 mg ascorbic acid) alone and in combination on the above variables in rotational depressed shift worker in Tehran Refinery. In first Beck Depression Inventory and the general questioner in all workers at operational and firefighting sites (456 people) will be distributed. People have entry criteria and no exclusion criteria were enrolled into the study. Inclusion criteria depression score equal to or more than 10 of the 21 item questionnaire Beck (beck) was agree to participate in research out of the presence of disease (thyroid, kidney, liver, diabetes, heart Cardiovascular, cancer, hypertension) based on the contents of employment records of individuals, as a professional exercise, smoking, alcohol consumption, drug materials, drug, or over two weeks before the study and taking supplements and drugs for depression at 2 months ago of study so 136 shift workers entered to intervention. Blood serum to measure these markers before and after intervention with 10-12 hours fasting in 7.30-8.30 the morning 8cc fasting blood can receive, 24 h food questionnaire data collected through interviews. be collected, diastolic blood pressure, weigh and high is measured to calculate BMI. During the study, subjects were asked not to change their diet. After explaining the study and how its implementation of all participants in the intervention, written consent was obtained for participation in research. For intervention research shift worker using a balanced block randomization method were divided into

4 groups. Omega-3 capsules and tablets appear to be different so, double-dummy technique was used in the study. In Group 1, 2 capsules omega-3 and 2 tablets of vitamin C and in Group 2, 2 capsules of omega-3 and 2 placebo tablet of vitamin C and group 3, 2 tablets of vitamin C and 2 placebo capsule of omega-3 in the group 4, 2 placebo capsule of omega-3 and 2 placebo tablet of vitamin C for every day in 2 months. this study approved by Medical Ethics Medical School University took place in Tehran.

General information

Acronym

IL-6 Interleukin 6-CRP C-Reactive Protein -BMI Body Mass Index--ROS Reactive Oxygen Speci

IRCT registration information

IRCT registration number: **IRCT201202189056N1**
Registration date: **2012-06-05, 1391/03/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-05, 1391/03/16

Registrant information

Name

Syed Bagher Mortazavi

Name of organization / entity

Tarbiat modares university

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 3825

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Recruitment status

Recruitment complete
Funding source
Tarbiat Modares University

Expected recruitment start date
2011-11-06, 1390/08/15

Expected recruitment end date
2012-04-03, 1391/01/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studies on the possible lowering of occupational errors by intervention on inflammatory, oxidative stress factors and depression in Tehran refinery oil shift workers treated with omega 3 and vitamin C.

Public title
Studies on the possible lowering of occupational errors by intervention on inflammatory, oxidative stress factors and depression in Tehran refinery oil shift workers treated with omega 3 and vitamin C.

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: -- Willingness to cooperate with research - Their depression score is higher than others
Exclusion criteria: - Liver disease, renal, cardiovascular and diabetes - Blood pressure drugs - Cigarettes and alcohol and drug - Taking vitamin supplements and omega - 3 - Taking antidepressant

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **136**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
for the first time

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tarbiat Modares University

Street address

Faculty of Medicine-Tarbiat Modares University- Near to Gisha bridge- Kargar shomali ave.Tehran

City

Tehran

Postal code

Approval date

2011-11-05, 1390/08/14

Ethics committee reference number

5321065

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.0 ,F32

ICD-10 code description

Mild and moderate depression

Primary outcomes

1

Description

Depression score

Timepoint

2 months

Method of measurement

Beck Depression Inventory

Secondary outcomes

1

Description

CORTISOL

Timepoint

2 months

Method of measurement

blood sample

2

Description

hs.CRP

Timepoint

2 months

Method of measurement

blood sample

3

Description

TAC

Timepoint

2 months

Method of measurement

blood sampling

4

Description

IL-6

Timepoint

2 months

Method of measurement

blood sampling

5

Description

MAD

Timepoint

2 months

Method of measurement

blood sampling

Intervention groups

1

Description

omega-3 1000mg(180 mg EPA and 120 mg DHA) vitamin C 250 mg every day 2 capsuls omega-3and 2 tablats vitamin C

Category

Treatment - Drugs

2

Description

omega-3 and placebo vitamin c

Category

Treatment - Drugs

3

Description

placebo omega-3 and vitamin C

Category

Treatment - Drugs

4

Description

placebo omega-3 and placebo vitamin c

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Tondgooian Tehran oil refinery

Full name of responsible person

Dr. Seyed Bagher Mortazavi

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Tarbiat Modares University- Near to Gisha bridge- Kargar shomali ave.Tehran

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tarbiat Modares University

Full name of responsible person

Mr. moosavian

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Grant name

پشتیبانی از پایان نامه ها و رساله ها

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tarbiat Modares University

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**

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Full name of responsible person

Farahnaz Khajehnasiri

Position

PhD candidate

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Associate professor

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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