

# 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

###### Email address

mortazav@modares.ac.ir

##### 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

**Street address**

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

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Mr. moosavian

**Street address**

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

**City**

Tehran

**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**

Tarbiat Modares University

**Full name of responsible person**

Farahnaz Khajehnasiri

**Position**

PhD candidate

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

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tarbiat Modares University

**Full name of responsible person**

Dr. Seyed Bagher Mortazavi

**Position**

Associate professor

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**City**

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**Postal code****Phone**

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**Fax****Email**

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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*