

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Effects of Probiotics on Mental Health, Serum Neuropeptide Y, CRP and INF- $\gamma$ , Kynurenine Pathway, Hypothalamus-Pituitary-Adrenal Axis Activity and Oxidative Stress in Workers of Petrochemical Company

#### Protocol summary

##### Summary

1- Objectives: Assessing the effect of probiotics on mental health, stress oxidative and inflammatory indices in Petrochemical staff; 2- Design: Double-blinded Randomized Clinical Trial; 3- Setting, conducting and intervention: To conduct this study, the staff of Petrochemical Research & Technology Co., aging between 20 - 60, was invited. After signing the Consent Form by the eligible persons, 35 labors were randomly divided into three groups, to receive "100 grams of probiotics yogurt + placebo" or "ordinary yogurt + probiotics supplement" or "ordinary yogurt + placebo" for 6 weeks. All three groups were advised not to change their normal diet or activities. Fasting blood tests were performed on all three groups before and after intervention. The 24-Hour Dietary Recall Questionnaire (to investigate the energy and nutritional intake), the International Physical Activity Questionnaire (IPAQ), and anthropometric data including weight, height, BMI and blood pressure have been completed at the beginning of the study and also at the end of the sixth week; 4- Main inclusion criteria: Having good physical health conditions and not taking any nutritional supplements in the last two months, and not taking any medicine (anti-depression, NSAID, etc.); Main exclusion criteria: Not following the treatment (using less than 80% of yogurts or supplements); 5- Main outcome measures: It seems that Probiotics causes the decrease in inflammatory factors and stress oxidative, and also have a positive effect on mental health.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201406222394N11**  
Registration date: **2014-12-02, 1393/09/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-12-02, 1393/09/11

##### Registrant information

###### Name

Shima Jazayeri

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8670 4805

###### Email address

sjazayeri@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

All costs of this study is born by "National Petrochemical Company of Iran"

##### Expected recruitment start date

2014-02-05, 1392/11/16

##### Expected recruitment end date

2014-03-19, 1392/12/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of Probiotics on Mental Health, Serum Neuropeptide Y, CRP and INF- $\gamma$ , Kynurenine

Pathway,Hypothalamus-Pituitary-Adrenal Axis Activity and Oxidative StressinWorkers of Petrochemical Company

## Public title

The Effect of Probiotics on Mental Health

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion Criteria: 1. Having the willingness to participate in the study and signing an informed consent form; 2. Having at least one-year work experience in Petrochemical Research & Technology Co.; 3. Aging between 20 and 60; 4. Having good physical health conditions based on the clinical history; 5. Not using nutritional supplements in the last 2 months; 6. Not taking medicines (anti-depression, NSAID, etc.); 7. GHQ score of equal or more than 9. Exclusion Criteria: 1. Smoking cigarettes in the last year; 2. Having an unwillingness to participate; 3. Not following the treatment (using less than 80% of yogurts or supplements); 4. Having physical sickness or taking any kind of medicine or supplements during the intervention.

## Age

From **20 years** old to **60 years** old

## Gender

Both

## Phase

2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **35**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

##### Street address

Floor 6, the Central Building of University, corner of Ghods St., Keshavarz Boulevard

##### City

Tehran

## Postal code

## Approval date

2013-05-21, 1392/02/31

## Ethics committee reference number

130/324/92/5

## Health conditions studied

### 1

#### Description of health condition studied

Healthy persons exposed to petrochemical pollutants.

#### ICD-10 code

Z57.5

#### ICD-10 code description

Occupational exposure to toxic agents in other industries

## Primary outcomes

### 1

#### Description

Fat intake

#### Timepoint

At the begining of the study and the end of 6th week.

#### Method of measurement

The 24-Hour Dietary Recall Questionnaire

### 2

#### Description

mental health

#### Timepoint

At the begining of the study and the end of 6th week.

#### Method of measurement

GHQ (General Health Questionnaire)

### 3

#### Description

Neuropeptide Y (NPY)

#### Timepoint

At the begining of the study and the end of 6th week.

#### Method of measurement

Blood Test

### 4

#### Description

CORTISOL

#### Timepoint

At the begining of the study and the end of 6th week.

#### Method of measurement

Blood Test

### 5

#### Description

( Adrenocorticotropic hormone)ACTH

#### Timepoint

At the begining of the study and the end of 6th week.

#### Method of measurement

Blood Test

## 6

### **Description**

carbonylated Protein

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

Blood Test

## 7

### **Description**

Kynurenine (KYN)

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

Blood Test

## 8

### **Description**

Isoprostane F2 $\alpha$

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

Blood Test

## 9

### **Description**

hydroxydeoxyguanosine (8-OHdG)

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

Blood Test

## 10

### **Description**

Oxidized low-density lipoprotein (Ox-LDL)

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

Blood Test

## 11

### **Description**

Interferon gamma (IFN $\gamma$ )

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

Blood Test

## 12

### **Description**

Tryptophan

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

Blood Test

## 13

### **Description**

Physical Activity

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

International Physical Activity Questionnaire(IPAQ)

## 14

### **Description**

Age

### **Timepoint**

Beginning of the study

### **Method of measurement**

Question

## 15

### **Description**

Height

### **Timepoint**

Beginning of the study

### **Method of measurement**

Height measurement with Seca Stadiometer

## 16

### **Description**

Body mass index (BMI)

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

Weight in Kilograms divided by height in meters squared( $\text{weight}(\text{kg})/[\text{height}(\text{m})^2]$ )

## 17

### **Description**

Energy intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## 18

### **Description**

Weight

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

Weight measurement with at least clothes by Seca Digital Scale with readability of 100g.

## 19

### **Description**

Protein intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **20**

### **Description**

Carbohydrate intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **21**

### **Description**

Saturated fat intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **22**

### **Description**

Mono-unsaturated fat intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **23**

### **Description**

Poly unsaturated fat intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **24**

### **Description**

Cholesterol intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **25**

### **Description**

Fiber intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **26**

### **Description**

Vitamin A intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **27**

### **Description**

Vitamin C intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **28**

### **Description**

Vitamin E intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **29**

### **Description**

Copper intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **30**

### **Description**

Selenium intake

### **Timepoint**

At the beginning of the study and the end of 6th week.

### **Method of measurement**

The 24-Hour Dietary Recall Questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

One capsule of placebo and 100 grams of ordinary yogurt.

#### **Category**

Placebo

### **2**

#### **Description**

Probiotics capsule twice a day and 100 grams of ordinary yogurt

#### **Category**

Treatment - Drugs

### **3**

#### **Description**

100 grams of probiotics yogurt and placebo

#### **Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Petrochemical Research & Technology Co.

**Full name of responsible person**

Mehdi Yosefi

**Street address**

Polymer & Petrochemical Research Institute, P.O. Box 14965/115, Research Blv., 15th km of Karaj Highway, Tehran, Iran.

**City**

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Petrochemical Research & Technology Co.+ Vice Chancellor of Research, Iran University of Medical Sc

**Full name of responsible person**

Esmail Ghanbari+ Dr. Seyed AliJavad Mousavi

**Street address**

No. 27, Sarve Alley, Southern Shirazi, Mollasadra, P.O. Box 14358, Tehran, Iran.+ Iran University of Medical Sciences, Hematt express way, Tehran ,Iran

**City**

Tehran

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

Yes

**Title of funding source**

Petrochemical Research & Technology Co.+ Vice Chancellor of Research, Iran University of Medical Sc

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Ali Akbar Mohammadi

**Position**

PhD student of Nutritional Sciences

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## Person responsible for scientific inquiries

### Contact

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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*