

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

**Comparing the effect of fish oil on the occurrence of atrial fibrillation with placebo (olive oil) after coronary artery bypass graft surgery in patients who are undergoing CABG surgery in the rajaei heart center in 2014, a randomized clinical trial**

### Protocol summary

#### Summary

This study is a randomized clinical trial in 392 patients scheduled for CABG surgery who referred to heart surgery clinic. After entering the study, using a randomized block, patients randomly entered into control and trial groups. 2000mg fish oil daily was given to the patients, twice a day (1 gr fish oil capsules each meal), containing 200 mg DHA and 300 mg EPA to intervention group and 2000 mg olive oil twice a day to placebo group. Intervention will begin at least 5 day before surgery and will continue for at least a week after surgery. Demographic data and other variables studied will be collected entering the study and during the study. In the open heart surgery ICU the patients will be monitored 24 hours. If AF occurs, start time and time of occurrence will be recorded. If patients have palpitations, ECG will be taken and if AF rhythm exists, will be recorded. Variables will be analyzed separately in the trial and placebo groups and results will be reported based on the information obtained.

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2013070713886N1**

Registration date: **2014-08-30, 1393/06/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

#### Registration date

2014-08-30, 1393/06/08

#### Registrant information

#### Name

Ali Vasheghani Farahani

#### Name of organization / entity

Tehran University of Medical Sciences

#### Country

Iran (Islamic Republic of)

#### Phone

+98 21 2392 2189

#### Email address

avasheghani@tums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2014-05-22, 1393/03/01

#### Expected recruitment end date

2014-08-23, 1393/06/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparing the effect of fish oil on the occurrence of atrial fibrillation with placebo (olive oil) after coronary artery bypass graft surgery in patients who are undergoing CABG surgery in the rajaei heart center in 2014, a randomized clinical trial

#### Public title

Comparing the effect of fish oil on the occurrence of atrial fibrillation with placebo (olive oil) after coronary artery bypass graft surgery in patients who are undergoing CABG surgery in the rajaei heart center in

2013, a randomized clinical trial

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
Inclusion criteria : All patients over 18 years old who are candidate for CABG surgery. Exclusion criteria: previous diagnosis of AF or atrial flutter; use of anti arrhythmic drugs (class 1&3) over the last 3 months; emergency surgery; MI over the last 2 weeks; emergency reoperation; post operative pacemaker placement; CABG and valve surgery; any conditions that can be effective on the digestion or absorption of food fatty acids; withdrew patients from continuing to participate in the study.

**Age**  
From **18 years** old to **99 years** old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **392**

**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

Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences, Taleghani st.,  
Ghods st., Enghelab square, Tehran

##### City

Tehran

##### Postal code

1417653761

##### Approval date

2014-03-01, 1392/12/10

##### Ethics committee reference number

105180

## Health conditions studied

### 1

#### Description of health condition studied

Post coronary artery bypass graft surgery atrial fibrillation.

#### ICD-10 code

I48

#### ICD-10 code description

Atrial fibrillation and flutter

## Primary outcomes

### 1

#### Description

Atrial fibrillation

#### Timepoint

After coronary artery bypass graft surgery AF

#### Method of measurement

Checking of patients rhythm in open heart surgery ICU

## Secondary outcomes

### 1

#### Description

Length of hospitalization

#### Timepoint

Time of discharge

#### Method of measurement

Patients records

## Intervention groups

### 1

#### Description

Intervention group: 1 gr fish oil pearls containing 300mg EPA and 200 mg DHA, twice a day , given the patients at least 5 day before surgery until time of discharge.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: 1 gr olive oil pearls , twice a day, given to the patients, at least 5 days before surgery until time of discharge.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rajaie Heart center

##### Full name of responsible person

Dr. Ali Vasheghani Farahani

##### Street address

Rajaie Heart center, Vali Asr st., Tehran  
**City**  
Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Tehan University of Medical Sciences  
**Full name of responsible person**  
Hajar Moammaie  
**Street address**  
Tehan University of Medical Sciences, Taleghani st.,  
Ghods st., Enghelab square, Tehran  
**City**  
Tehran  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Tehan 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

### Contact

**Name of organization / entity**  
Tehan University of Medical Sciences  
**Full name of responsible person**  
Awat Yousefi Azar  
**Position**  
Msc in critical care nursing  
**Other areas of specialty/work**  
**Street address**  
No 2, Derakhti alley, Nazari alley, South Madani st.  
**City**  
Tehran  
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**Email**  
a.youa@yahoo.com; aya.intensivist@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Tehan University of Medical Sciences  
**Full name of responsible person**  
Ali Vasheghani Farahani  
**Position**  
Fellowship of electrophysiology  
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**Email**  
avasheghani@tums.ac.ir  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehan University of Medical Sciences  
**Full name of responsible person**  
Awat Yousefi Azar  
**Position**  
Msc in critical care nursing  
**Other areas of specialty/work**  
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**Fax**  
**Email**  
a.youa@yahoo.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*