

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### A Clinical Trial Comparing the Effect of Omega-3 with Sertraline and Placebo on Depression General Health Conditions Among Dialysis Patients

#### Protocol summary

##### Summary

depression is very common in hemodialysis patients. it has been showed that depression is significantly related to the morbidity and mortality of these patients. In our randomized single blind controlled trial we compare the efficacy of Omega 3 as a known antidepressant agent with Sertraline, another antidepressant drug with known effect on depression in hemodialysis patients We also evaluate the effect of these drugs on general health conditions of these patients by their effects on Hemoglobin level. In our study a total number of 75 patients will randomized in 3 groups . In Omega 3 group the patients will receive 1500 mg of this drug in 3 divided doses. Sertraline will be given to this group patients in the dose of 50-150 Mg daily. The patients in all groups will receive the medications for 3 months and they will be evaluated at weeks 4,8 and 12 by appropriate clinical and laboratory tests. The results will be analysed and the data will be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201201175113N2**

Registration date: **2012-02-02, 1390/11/13**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-02-02, 1390/11/13

##### Registrant information

##### Name

Seyyed Mohammad Reza Khatami

##### Name of organization / entity

Nephrology Research Center, Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2659

##### Email address

khatamis@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

by a grant of Nephrology Research Center, Tehran University of Medical Sciences

##### Expected recruitment start date

2012-02-04, 1390/11/15

##### Expected recruitment end date

2012-05-03, 1391/02/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A Clinical Trial Comparing the Effect of Omega-3 with Sertraline and Placebo on Depression General Health Conditions Among Dialysis Patients

##### Public title

Treatment of Depression In Hemodialysis Patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion criteria: age more than 18 ; patients with depression; patients on hemodialysis exclusion criteria: use of anti depressant drugs during last 3 months ; participation in related trials in last 3 months ; not

cooperative patients ; not signing the consent.

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 75

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

ethic committee of research deputy of Tehran  
University of Medical Sciences

###### Street address

keshavarz blvd., central building of Tehran University  
of Medical Sciences

###### City

Tehran

###### Postal code

##### Approval date

2010-09-23, 1389/07/01

##### Ethics committee reference number

1473

### Health conditions studied

#### 1

##### Description of health condition studied

End Stage Renal Disease

##### ICD-10 code

N18.5

##### ICD-10 code description

Chronic kidney disease, stage 5 on dialysis

#### 2

##### Description of health condition studied

depression

##### ICD-10 code

F32.9

##### ICD-10 code description

Depressive episode, unspecified

### Primary outcomes

#### 1

##### Description

depression

##### Timepoint

time 0 and then weeks 4,8,12

##### Method of measurement

Hospital Depression Rating Scales test and SADS

### Secondary outcomes

#### 1

##### Description

Hemoglobin level

##### Timepoint

At time 0 and at the end of study

##### Method of measurement

Laboratory evaluation

### Intervention groups

#### 1

##### Description

group 1(treatmen group) : omega 3 1500 mg daily

##### Category

Treatment - Drugs

#### 2

##### Description

group intervention : sertralin 50-150 mg daily

##### Category

Treatment - Drugs

#### 3

##### Description

group 3 (control) : placebo

##### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Imam Khomeini hospital

###### Full name of responsible person

Seyyed Mohammad Reza Khatami

###### Street address

Imam Khomeini hospital, Keshavarz blvd

###### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Nephrology Research Center, Tehran University of Medical Sciences

**Full name of responsible person**

Seyyed Mohammad Reza Khatami

**Street address**

Imam Khomeini hospital, Keshavarz Blvd

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Nephrology Research Center, Tehran 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**

Nephrology Research Center, Tehran University of Medical Sciences

**Full name of responsible person**

Seyyed Mohammad Reza Khatami

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

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khatamis@sina.tums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Rouzbeh Hospital

**Full name of responsible person**

Seyyed Mohammad Araghi

**Position**

psychiatric assistant

**Other areas of specialty/work**

**Street address**

South Karegar Ave.

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+98 912 159 4326

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**Email**

smdaraghi@gmail.com

**Web page address**

## Person responsible for updating data

### Contact

## 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*