

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

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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

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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

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South Karegar Ave.

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+98 912 159 4326

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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