Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Sertraline effect on serum level of IL-6, IL-10, TNF-α, hsCRP, Albumin and Hemoglobin in Haemodialysis patients with depression

Protocol summary

Summary

The main aim of this study is to evaluate the antiinflammatory effect of Sertraline in haemodialysis patients with depression. Fifty adult patients with depression based on Beck Depression Inventory (BDI) are randomized to receive sertraline (50 to 200 mg orally once daily) (n = 25) or placebo (n = 25) for 3 month duration. Blood sampling are performed at baseline (before starting sertraline) and 6 and 12 weeks after sertraline and placebo treatment. Inflammatory cytokines, albumin, hemoglobin and hs-CRP are measured for all patients. Demographic & Clinical data regarding the cause of renal failure, current medications, the most recent laboratory values (taken within the past 1 month) and extrarenal co-morbidities such as diabetes mellitus, hypertension, atherosclerotic vascular disease, cardiac failure, cardiac valvular diseases, chronic lung diseases, and chronic hepatitis were obtained from the patient's medical records.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111228171N1**
Registration date: **2012-02-23, 1390/12/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-02-23, 1390/12/04

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Nephrology Research Center, Tehran University of Medical Sciences

Expected recruitment start date

2012-04-21, 1391/02/02

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Sertraline effect on serum level of IL-6, IL-10, TNF-α, hsCRP, Albumin and Hemoglobin in Haemodialysis patients with depression

Public title

AntiInflammatory effect of Sertraline in haemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- Age between 18 to 80 years; 2- start to Haemodialysis of at least 3 months duration; 3- Receiving maintenance haemodialysis, 4 hour three times per week via a low flux polysulphone dialyser using bicarbonate dialysis fluid; 4- presence of depression based on Beck Depression Inventory (BDI). Exclusion criteria : 1- Patients with major acute infections,

autoimmune disease, cancer, severe mental illness, cognitive dysfunction; 2- taking immunosuppressive agents like corticoestroieds for at least 1 month; 3- taking antiinflammatory drugs such as NSAIDs 3-Current use of an antidepressant medication; 4-Intolerance of Sertraline adverse effects.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Central organization 6th Floor, Tehran University of Medical sciences, Keshavarz Blvd.

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Tehran

Postal code

Approval date
2011-07-04, 1390/04/13

Ethics committee reference number
90041414797

Health conditions studied

1

Description of health condition studied
depression

ICD-10 code
F32

ICD-10 code description
Depressive episode

Primary outcomes

1

Description
Depression

Timepoint
Baseline, 6 and 12 weeks after

Method of measurement
Beck Depression Inventory (BDI)

Secondary outcomes

1

Description
Inflammation stutus

Timepoint
Baseline, 6 and 12 weeks after

Method of measurement
Inflammatory Cytokines (TNF-a, IL-6, IL-10, hs-CRP)

Intervention groups

1

Description
Intervention group: sertraline 50 to 200mg orally per day

Category
Treatment - Drugs

2

Description
Control group: Placebo 50 to 200 mg orally per day

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Haemodialysis center of Tehran Imam Khomayni Hospital complex

Full name of responsible person
Simin Dashti

Street address
Imam Khomayni Hospital Complex

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotoohi
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Enghelab Ave
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Tehran
Grant name
90/203/2543
Grant code / Reference number
2543
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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

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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