

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Evaluation of Sertraline effect on serum level of IL-6, IL-10, TNF- $\alpha$ , 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

##### Name

Mohammad Taraz

##### Name of organization / entity

Tehran university of medical sciences

##### Country

Iran (Islamic Republic of)

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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- $\alpha$ , 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 corticosteroids 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.

**City**

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 status

**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  
**Street address**  
Enghelab Ave  
**City**  
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

### Contact

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## Person responsible for scientific inquiries

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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*