

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### the effect of sertraline in dialysis associated hypotension

#### Protocol summary

##### Summary

The objective of this randomized, single blind trial is to investigate the effect of sertraline on dialysis associated hypotension. In this study 20 patients who meet the inclusion/exclusion criteria will be recruited and randomly assigned into intervention or control group. The patients in the intervention group will receive sertraline. The patients in the control group will receive placebo. before dialysis blood pressure, lowest blood pressure during dialysis, after dialysis blood pressure, number of therapeutic intervention will be measured before and after the intervention and compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112033043N3**  
Registration date: **2012-01-06, 1390/10/16**  
Registration timing: **retrospective**

Last update:  
Update count: **0**

##### Registration date

2012-01-06, 1390/10/16

##### Registrant information

###### Name

Simin Dashti-Khavidaki

###### Name of organization / entity

Tehran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6695 4709

###### Email address

dashtis@sina.tums.ac.ir

#### Recruitment status

##### Recruitment complete

##### Funding source

Tehran University of Medical Science and Health Services

##### Expected recruitment start date

2011-10-23, 1390/08/01

##### Expected recruitment end date

2011-12-11, 1390/09/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

the effect of sertraline in dialysis associated hypotension

##### Public title

the effect of sertraline in dialysis associated hypotension

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

inclusion: patient suffer from dialysis associated hypotension  
exclusion: systolic dysfunction, patients who can not tolerate sertraline's adverse effect, refusal to participate in the study, usage of midodrin

##### Age

No age limit

##### Gender

Both

##### Phase

N/A

##### Groups that have been masked

No information

##### Sample size

Target sample size: **20**

##### 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**

Tehran University of Medical Science and Health Services

**Street address**

Tehran University of Medical Science and Health Services, Poorsina Avenue

**City**

tehran

**Postal code****Approval date**

2011-11-26, 1390/09/05

**Ethics committee reference number**

90-8-21:1-8

**Health conditions studied****1****Description of health condition studied**

dialysis associated hypotension

**ICD-10 code**

Y84.1.I95

**ICD-10 code description**

Kidney dialysis.Hypotension

**Primary outcomes****1****Description**

hypotension

**Timepoint**

4weeks before intervention,during intervention,4weeks after intervention

**Method of measurement**

mmhg with use of digital barometer

**Secondary outcomes****1****Description**

complications of hypotension such as cramp,dizziness,headache,neusea and vomiting,

**Timepoint**

4weeks before intervention,during intervention,4weeks after intervention

**Method of measurement**

observation

**Intervention groups****1****Description**

treatment group:administration tablet of sertraline 50-100mg once daily for 8 weeks

**Category**

Treatment - Drugs

**2****Description**

control group:administration placebo of sertraline 50-100mg once daily for 8 weeks

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomeini hospital

**Full name of responsible person**

Dr.Simin Dashti-Khavidaki

**Street address**

Dr Gharib Avenue,Keshavarz Boulevard

**City**

tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Science and Health Services

**Full name of responsible person**

Dr.Simin Dashti-Khavidaki

**Street address**

Department of clinical pharmacy, Faculty of pharmacy, Tehran University of Medical Science and Health Services, Poorsina Avenue

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tehran University of Medical Science and Health Services

**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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Science and Health Services

**Full name of responsible person**

Dr.Simin Dashti-Khavidaki

**Position**

associated professor in clinical pharmacy

**Other areas of specialty/work****Street address**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Science and Health Services

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**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*