

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of Sertraline effect for Intradialytic Hypotension in the dialytic patients that has been referred to dialyse department of Kowsar hospital in Semnan

Protocol summary

Summary

Objective: evaluation the effect of sertraline on hypotension during hemodialysis in dialysis patients referred to Semnan Kowsar hospital Study design: Random (random blocks), one blind side, control with placebo, single central Experimental population: at least 100 persons of hemodialysis patients in Semnan Kowsar hospital Inclusion criteria: Permanent hemodialysis patients for the at least 3 months that in at least 50 percent of their hemodialysis cases in last 3 months, having intra-dialytic hypotension; perform at least 4 hours hemodialysis for 3 times per week; concentration of dialysis fluid: Na: 106 mEq/L, Ca: 5.2 mEq/L, K: 2 mEq/L and mg: 1 mEq/L, Cl: 111.5 mEq/L, HCO₃ 3.35; fluid dialysis flow: 500 to 600 ml/min; blood flow: 250 to 300 ml/min; antihypertensive agents received during dialysis; available for at least 8 weeks (study time). Exclusion criteria: Performing hemodialysis in different treatment centers during the time of the study; having mental illness that use the SSRIs drug. Sample size, intervention, intervention time and outcome of the study: sample size of this study is 100 persons will be divided into intervention and control group. Intervention group: receive sertraline 50 mg daily (manufactured by Hayan Darou Company) in during first week and it is increased to 100 mg daily and patients are received sertraline 100 mg daily for another 3 weeks (total 4 weeks: due to that sertraline useful times of effectiveness is 4 weeks) Control group: receive one placebo tablet daily (totally like sertraline but without therapeutic properties) for 4 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080625732N23**

Registration date: **2017-08-15, 1396/05/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-15, 1396/05/24

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2017-01-04, 1395/10/15

Expected recruitment end date

2018-01-05, 1396/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Sertraline effect for Intradialytic Hypotension in the dialytic patients that has been

referred to dialyse department of Kowsar hospital in Semnan

Public title
Evaluation of Sertraline effect for Intradialytic Hypotension in the dialytic patients that has been referred to dialyse department of Kowsar hospital in Semnan

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Permanent hemodialysis patients for the at least 3 months that in at least 50 percent of their hemodialysis cases in last 3 months, having intra-dialytic hypotension; perform at least 4 hours hemodialysis for 3 times per week; concentration of dialysis fluid: Na: 106 mEq/L, Ca: 5.2 mEq/L, K: 2 mEq/L and mg: 1 mEq/L, Cl: 111.5 mEq/L, HCO₃ 3.35; fluid dialysis flow: 500 to 600 ml/min; blood flow: 250 to 300 ml/min; antihypertensive agents received during dialysis; available for at least 8 weeks (study time). Exclusion criteria: Performing hemodialysis in different treatment centers during the time of the study; having mental illness that use the SSRIs drug.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

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

Ethics Committee, Deputy of research and technology, Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan
Postal code
3514799442
Approval date
2017-01-03, 1395/10/14
Ethics committee reference number
IR.semums.REC.1395.156

Health conditions studied

1

Description of health condition studied

hypotension

ICD-10 code

I95.9

ICD-10 code description

Hypotension, unspecified

Primary outcomes

1

Description

Serum creatinine level

Timepoint

Before, 12, 24 and 48 hours after intervention

Method of measurement

Exam

2

Description

Blood Urea Nitrogen (BUN)

Timepoint

Before, 12, 24 and 48 hours after intervention

Method of measurement

Exam

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive sertraline 50 mg daily (manufactured by Hayan Darou Company) in during first week and it is increased to 100 mg daily and patients are received sertraline 100 mg daily for another 3 weeks (total 4 weeks: due to that sertraline useful times of effectiveness is 4 weeks)

Category

Treatment - Drugs

2

Description

Control group: receive one placebo tablet daily (totally like sertraline but without therapeutic properties) for 4

weeks.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Maliheh Yarmohammadi

Street address

Kosar Hospital, Street Amin, Semnan

City

Semnan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences, Deputy of
Research and Technology

Full name of responsible person

Mohammadreza Asgari

Street address

Semnan University of Medical Sciences, Deputy of
Research and Technology, Basij Blvd, Semnan

City

Semnan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan University of Medical Sciences, Deputy of
Research and Technology

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

Semnan University of Medical Sciences

Full name of responsible person

Maliheh Yarmohammadi

Position

Kidney and urethra

Other areas of specialty/work

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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