# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

# Evaluation of vasopressin nasal spray effect on the amount of hypertonic saline required for the treatment of intradialytic hypotension in End-stage renal disease patients

## Protocol summary


**Summary**

This study aimed to evaluate vasopressin nasal spray's effect on amount of hypertonic saline required for the treatment of intradialytic hypotension and the incidence of intradialytic hypotension in End-stage renal disease patients. All patients with ESRD undergoing hemodialysis in the hemodialysis ward of Ali ibn Abitalib hospital in zahedan with known symptomatic episodes of intradialytic hypotension in at least 30 % of hemodialysis sessions in the 30 days preceding of study, enrolled to study. Patients with the simultaneous use of other preventive methods for intradialytic hypotension, excluded from study. 15 patients in the interventional group received two puffs of vasopressin nasal spray (Minirin®, 10 µg) 30 minutes before hemodialysis for a month and then as the control group received placebo nasal spray (NaCl 0.9 %) 30 minutes before hemodialysis for a month. Systolic blood pressure and mean arterial blood pressure were measured before dialysis and 1, 2, 3 and 4 hours after dialysis start. A fall in systolic blood pressure by at least 20 mmHg or a decrease in mean arterial pressure by at least 10 mmHg with clinical symptoms of hypotension were considered as intradialytic hypotension. Treatments and given saline volumes were recorded and compared between the two groups.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2015060222540N1**
Registration date: **2015-07-06, 1394/04/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2015-07-06, 1394/04/15

**Registrant information**


**Name**

Iman Poorkeykhaei

**Name of organization / entity**

Zahedan university of medical sciences

**Country**

Iran (Islamic Republic of)

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**Email address**

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**Recruitment status**

**Recruitment complete**

**Funding source**

All costs of this study will be paid by the researcher.

**Expected recruitment start date**

2015-02-09, 1393/11/20

**Expected recruitment end date**

2015-04-20, 1394/01/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of vasopressin nasal spray effect on the amount of hypertonic saline required for the treatment of intradialytic hypotension in End-stage renal disease patients

**Public title**

The effect of vasopressin nasal spray on intradialytic hypotension

**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: ESRD patients with known symptomatic episode of intradialytic hypotension in at least 30% of hemodialysis sessions in the 30 days preceding enrollment; Serum sodium levels greater than 140 mEq/L. Exclusion criteria: History of ischemic heart desease; History of cardiovascular events (MI, CVA, ...); Anemia (HB<10 g/dL); Usage of other treatments for intradialytic hypotension at the same time
**Age**
From **15 years** old to **70 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **15**
**Randomization (investigator's opinion)**
N/A
**Randomization description**
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Single
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Zahedan University of Medical Sciences
**Street address**
Khalij Fars highway - Zahedan University of Medical Sciences
**City**
Zahedan
**Postal code**
**Approval date**
2015-02-04, 1393/11/15
**Ethics committee reference number**
5922

## Health conditions studied

### 1

**Description of health condition studied**
End stage renal desease patients who underwent hemodialysis treatment
**ICD-10 code**
N18.5
**ICD-10 code description**
Chronic kidney disease, stage 5

### 2

**Description of health condition studied**
Intradialytic hypotension
**ICD-10 code**
I95.8
**ICD-10 code description**
Other hypotension

## Primary outcomes

### 1

**Description**
Intradialytic Hypotension
**Timepoint**
Before hemodialysis and 1, 2, 3 ,4 hours after the start of hemodialysis start
**Method of measurement**
By Mercury sphygmomanometer - A fall in Systolic Blood Pressure by at least 20 mmHg or a decrease in mean arterial pressure by at least 10 mmHg with clinical symptomes of hypotension after onset of hemodialysis

### 2

**Description**
Saline volume
**Timepoint**
After intradialytic hypotension occures and needes intervertion
**Method of measurement**
By the given volume of saline (mL)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention: Vasopressin nasal spray, 20 micrograms, 30 minutes before the start of hemodialysis start, for 30 days
**Category**
Treatment - Drugs

### 2

**Description**
Control: Nacl Nasal spary, 30 minutes before the start of hemodialysis, for 30 days
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Hemodialysis ward of Ali ibn Abi Talib hospital in zahedan
**Full name of responsible person**
Dr Ali Alidadi
**Street address**
Khalij Fars highway - Ali ibn Abi Talib hospital
**City**
Zahedan

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
All costs of this study were be paid by the researcher
**Full name of responsible person**
Dr Ali Alidadi
**Street address**
khalij fars highway - Ali ibn abi talib hospital
**City**
Zahedan
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
All costs of this study were be paid by the researcher
**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**
Zahedan University of Medical Sciences
**Full name of responsible person**
Dr Ali Alidadi
**Position**
Nephrologist
**Other areas of specialty/work**
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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*