

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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

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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 disease; 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 disease 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 symptoms of hypotension after onset of hemodialysis

2

Description

Saline volume

Timepoint

After intradialytic hypotension occurs and needs intervention

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 spray, 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

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khalij fars highway - Ali ibn abi talib hospital

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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

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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