

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Study of the effect of intensive dialysis and Hb correction in ESRD patient with high LVEDP and high pulmonary hypertension

#### Protocol summary

##### Study aim

Effect of intensive dialysis and Hb correction in ESRD patient with high LVEDP and high pulmonary hypertension

##### Design

The present study is a pre-and post-intervention clinical trial that will be performed on hemodialysis patients with ESRD and high-level of PH. intervention is intensive hemodialysis (hemodialysis treatment  $\geq$  16 hours per week) and hemoglobin correction (erythropoietin injection (rhEPO)).

##### Settings and conduct

The present study is a pre-and post-intervention clinical trial that will be performed on hemodialysis patients with ESRD and high-level of PH who are referred to Imam Khomeini, Golestan and Razi hospitals in Ahwaz. A double-blind Doppler echocardiography will be done for all patients before intensive hemodialysis and in follow-up study after dialysis. the result of Chest echocardiography is used to determine pulmonary blood pressure (PAP) and left ventricular function. In this study, the systolic pulmonary artery pressure greater than 35 mmHg is defined as the criterion for the presence of pulmonary hypertension

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age over 18 years - SPAP > 35 mm Hg - Serum creatinine 6-2 mg / dL - consent to participate in the study  
Exclusion criteria: - The presence of parenchymal and vascular diseases such as acute or chronic PET and COPD that individually causes PH - The presence of acute valve illnesses that individually increase the pH, such as Flail MV Leaflet - Patients with recent MI - Patients who have received blood during the study or who have an acute illness that causes hematocrit changes, such as acute bleeding

##### Intervention groups

intensive hemodialysis and hemoglobin correction

##### Main outcome variables

PAP; LVEF; systolic; diastolic function LV; GLS

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180212038705N1**

Registration date: **2018-02-27, 1396/12/08**

Registration timing: **prospective**

Last update: **2018-02-27, 1396/12/08**

Update count: **0**

##### Registration date

2018-02-27, 1396/12/08

##### Registrant information

##### Name

Fariba Heidari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3338 2242

##### Email address

heidari.p@ajums.ac.ir

##### Recruitment status

**Not yet recruiting**

##### Funding source

##### Expected recruitment start date

2639-05-22, 2018/03/01

##### Expected recruitment end date

2639-11-19, 2018/08/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of the effect of intensive dialysis and Hb correction in ESRD patient with high LVEDP and high pulmonary hypertension

2018-01-23, 1396/11/03

**Ethics committee reference number**  
IR.ajums.REC.1396.911

**Public title**

Effect of intensive dialysis and Hb correction in ESRD patient

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

SPAP> 35 mm Hg Cr 2-6 mg/dL age >18 Hemodialysis patients with ESRD

**Exclusion criteria:**

Acute or chronic PET and COPD Severe valvular disease Patients with recent MI Acute bleeding

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

N/A

**Randomization description**

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Other

**Other design features**

This study is a clinical trial with before and after intervention (Self-control method)

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Ahvaz Jundishapour University of Medical Sciences

**Street address**

Ahvaz, Golestan, Jundishapour University of Medical Sciences

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

61355393

**Approval date**

**Health conditions studied**

1

**Description of health condition studied**

End Stage Renal Disease

**ICD-10 code**

N18.5

**ICD-10 code description**

Chronic kidney disease, stage 5

**Primary outcomes**

1

**Description**

PAP

**Timepoint**

Before and after hemodialysis

**Method of measurement**

Chest doppler echocardiography

2

**Description**

LV function

**Timepoint**

Before and after hemodialysis

**Method of measurement**

echocardiography

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group: ESRD patients after hemodialysis and hemoglobin modification

**Category**

Treatment - Other

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital

**Full name of responsible person**

Dr. Nehzat Akiash

**Street address**

Imam Khomeini Hospital, Azadegan Ave

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## 2

### Recruitment center

**Name of recruitment center**  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Dr. Nehzat Akiash  
**Street address**  
Jundishapur University of Medical Sciences, Golestan Highway  
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drdarabi01@gmail.com  
**Web page address**  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Ahvaz University of Medical Sciences  
**Proportion provided by this source**  
100  
**Public or private sector**

Public  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Dr. Nehzat Akiash  
**Position**  
Associate Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Cardiology  
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## Person responsible for scientific inquiries

### Contact

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Forogh Darabi  
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Resident  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Forough Darabi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

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**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available