Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-leve of PH. interventon is intensive hemodialysis (hemodialysis treatment ≥ 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

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Iran (Islamic Republic of)

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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

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 clronic 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
Khouzestan
Postal code
61355393
Approval date
2018-01-23, 1396/11/03
Ethics committee reference number
IR.ajums.REC.1396.911

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
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2

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Sponsors / Funding sources

1

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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
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
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Dr. Nehzat Akiash
Position
Associate Professor
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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