Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial of effect of lower limb bioimpedance spectroscopy on determining patients' dry weight and their cardiovascular parameters in patients with chronic kidney disease under hemodialysis.

Protocol summary

Summary

The goal of our study is to assess patient 's dry weight with lower limb bioimpedance spectroscopy to better determination of serum pro b-type natriuretic peptide (ProBNP) and patients' blood pressure changing. Design: Interventional without control group. Population: Patients with chronic kidney disease under hemodialysis. All 53 patients selected for study, will be included in intervention group. Blinding do not be applied in our study. All subjects will be included in the intervention group and randomization Will not be applicable. Inclusion criteria: Patients older than 18 years old who have the history of dialysis for more than 3 months. Exclusion criteria: Psychiatric diseases; pregnancy; breastfeeding; stage 4 of congestive heart failure; positive history of myocardial infarction or stroke in past 6 months; having cardiac pacemaker or implant; having knee or hip implant; having deep venous thrombosis or lymph edema in lower limb. At first, hemodialysis patients in one dialysis session (or more session) are placed constantly under lower limb bioimpedance spectroscopy. When external resistance of lower limb's cells reaches to a plateau state , this point is patient 's dry weight. After reaching the patients' dry weight, bioimpedance will be repeated after three months and six months. Patients' weight and blood pressure will be monitored before and after patients' dialysis. Serum pro b-type natriuretic peptide (ProBNP) will be measured at baseline and at six months later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090329587N2**
Registration date: **2016-10-09, 1395/07/18**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-10-09, 1395/07/18

Registrant information

Name

Mohamadtaghi Najafi

Name of organization / entity

Nephrology research center, Emam Khomeyni hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 6659 5910

Email address

rabedini@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences.

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of effect of lower limb bioimpedance spectroscopy on determining patients' dry weight and their cardiovascular parameters in patients with chronic kidney disease under hemodialysis.

Public title
Effect of lower limb bioimpedance spectroscopy on determining patient 's dry weight and their cardiovascular parameters.
Purpose
Diagnostic
Inclusion/Exclusion criteria
Inclusion criteria: Patients older than 18 years old who have the history of dialysis for more than 3 months. Exclusion criteria: Psychiatric diseases; pregnancy; breastfeeding; stage 4 of congestive heart failure; positive history of myocardial infarction or stroke in past 6 months; having cardiac pacemaker or implant; having knee or hip implant; having deep venous thrombosis or lymph edema in lower limb.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **53**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences.
Street address
Ethics committee of Tehran University of Medical Sciences, Number 23, 4th Floor, 16 Azar street, Keshavarz Blvd,Tehran.
City
Tehran
Postal code
Approval date
2015-11-25, 1394/09/04
Ethics committee reference number
IR.TUMS.REC.1394.1271

Health conditions studied

1

Description of health condition studied
Patients with chronic kidney disease under hemodialysis..
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5.

Primary outcomes

1

Description
Dry weight.
Timepoint
During at frist session of hemodialysis, at third month after patient reaches to her or his gaol dry weight, at sixth month after patient reaches to her or his gaol dry weight.
Method of measurement
Lower limb bioimpedance spectroscopy.

2

Description
Pro b-type Natriuretic Peptide.
Timepoint
At baesline and at the end of study (when patient entry to our study and six month later when the study end).
Method of measurement
blood analysis

Secondary outcomes

1

Description
Blood pressure.
Timepoint
Before and after dialysis.
Method of measurement
Physical examination with sphengomanometer.

2

Description
Sodium.
Timepoint
Every month during study.
Method of measurement
blood analysis

3

Description
Potassium.
Timepoint
Every month during study.

Method of measurement
blood analysis

4

Description
Adequacy of dialysis.
Timepoint
Every month during study.
Method of measurement
With measurement of blood urea before and after dialysis and approciate formula for calculation of adequacy of dialysis (Kt/v formula).

5

Description
Albumin.
Timepoint
Every month during study.
Method of measurement
blood analysis

6

Description
Blood lipids (triglycerides, cholesterol).
Timepoint
Every month during study.
Method of measurement
blood analysis

7

Description
Complete blood count.
Timepoint
Every month during study.
Method of measurement
blood analysis

8

Description
Fasting blood glucose.
Timepoint
Every month during study.
Method of measurement
blood analysis

9

Description
Creatinine.
Timepoint
Every month during study.
Method of measurement
blood analysis

10

Description
Urea.
Timepoint
Every month during study.
Method of measurement
blood analysis

Intervention groups

1

Description
Intervention: Determining patient's dry weight with lower limb bioimpedance spectroscopy. Lower limb bioimpedance spectroscopy will be done at supine position in the time of dialysis. Calf resistance will be monitored every 30 minutes in the time of dialysis until extracellular resistance persists despite ultrafiltration continuing. This number represents the estimated dry weight which is determined using bioimpedance spectroscopy. If the patient does not reach the goal dry weight, end dialytic target weight will be reduced 0.2-0.5 Kg in next dialysis sessions. Dry weight will be determined with bioimpedance spectroscopy once at the end of third month after patient reaches the goal dry weight and once at the end of the study (at sixth month). Also, the goal weight will be changed if needed.
Category
Diagnosis

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam hospital.
Full name of responsible person
Dr. Mohamadtaghi Najafi.
Street address
Imam hospital, Keshavarz blvd, Tehran.
City
Tehran.

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Tehran University of Medical Sciences.
Full name of responsible person
Kardan.
Street address
Vice chancellor for research, 6 th floor, Central building of Tehran University of Medical Sciences, Ghods street, Keshvarz Blvd, Tehran
City
Tehran.
Grant name
-
Grant code / Reference number
-

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Tehran University of Medical Sciences.
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
Imam hospital.
Full name of responsible person
Dr. Mohamadtaghi Najafi.
Position
Associate professor in nephrology center.
Other areas of specialty/work
Street address
Imam hospital, Keshavarz blvd, Tehran.
City
Tehran.
Postal code
1419733141
Phone
+98 21 6659 5910
Fax
+98 21 6659 5910
Email
motanjf@gmail.com
Web page address
-

Person responsible for scientific inquiries

Contact
Name of organization / entity
Imam hospital.
Full name of responsible person
Dr. Mohamadtaghi Najafi.
Position
Associate professor in nephrology center.
Other areas of specialty/work
Street address
Imam hospital, Keshavarz blvd, Tehran.
City
Tehran.
Postal code
1419733141
Phone
+98 21 6659 5910
Fax
+98 21 6659 5910
Email
motanjf@gmail.com
Web page address
-

Person responsible for updating data

Contact
Name of organization / entity
Imam hospital.
Full name of responsible person
Dr. Mohamadtaghi Najafi.
Position
Associate professor in nephrology center.
Other areas of specialty/work
Street address
Imam hospital, Keshavarz blvd, Tehran.
City
Tehran.
Postal code
1419733141
Phone
+98 21 6659 5910
Fax
+98 21 6659 5910
Email
motanjf@gmail.com
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