

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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 appropriate 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
empty

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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr. Mohamadtaghi Najafi.

Position
Associate professor in nephrology center.

Other areas of specialty/work

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Person responsible for updating data

Contact

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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