

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Effect of incentive spirometry to ventilation of hemodialysis patients

Protocol summary

Summary

Hemodialysis patients experience a variety of complications one of the complications is respiratory system disorder. The incentive spirometer can help hemodialysis patients to improve their respiratory status. The main goal of this research is to determine the effect of Incentive spirometry on pulmonary ventilation of hemodialysis patients. and sub goals is : 1. Determine and compare the FVC, FEV1, FEV1/FVC before the study, in the intervention and control groups. 2. Determine and compare the FVC, FEV1, FEV1/FVC month after the intervention, in the intervention and control groups. 3. Determine and compare the FVC, FEV1, FEV1/FVC, two months after the intervention, in the intervention and control groups. 4. Comparison of FVC, FEV1, FEV1/FVC before the study, one month and two months after in the intervention group 5. Comparison of FVC, FEV1, FEV1/FVC before the study, one month and two months after the intervention in the control group 6. Determine and compare the average distance over 6 minutes walk before, one month and two months after in the intervention and control groups Participants must be at least 6 months of hemodialysis treatment. Inclusion criteria: completely satisfactory cooperation; ability to perform spirometry; normal chest and spine according to the patient stated; minimum age 18 years; hemodialysis three times a week; hemodialysis for at least 6 months; no history of chronic lung disease; absence of valvular heart disease; CHF; cardiac arrhythmia; high blood pressure of 100/180 and lower than 60/100. Exclusion criteria: severe disability; the patient's unwillingness to cooperate; cardiac surgery or chest area Lung volumes and the distance in 6 minutes walking measured initially in the participants, and then use of incentive spirometry applies for two months as intervention. One and two months after the intervention indicators are measured and compared with before the intervention. Expected to improve lung volumes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201208052226N10**

Registration date: **2012-10-15, 1391/07/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-10-15, 1391/07/24

Registrant information

Name

Mansooreh Aliasgharpour

Name of organization / entity

Nursing & midwifery faculty, Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-03-19, 1390/12/29

Expected recruitment end date

2012-10-21, 1391/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of incentive spirometry to ventilation of hemodialysis patients

Public title

Effect of incentive spirometry to ventilation of hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: completely satisfactory cooperation; ability to perform spirometry; normal chest and spine according to the patient stated; minimum age 18 years; hemodialysis three times a week; hemodialysis for at least 6 months; no history of chronic lung disease; absence of valvular heart disease; CHF; cardiac arrhythmia; high blood pressure of 100/180 and lower than 60/100. Exclusion criteria: severe disability; the patient's unwillingness to cooperate; cardiac surgery or chest area during the study; patient die during the study and acute complications of pulmonary infection during the study.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Science

Street address

Faculty of Nursing and Midwifery, Eastern-Nosrat Stereet, Tohid Sq., Tehran, Iran.

City

Tehran

Postal code**Approval date**

2010-09-23, 1389/07/01

Ethics committee reference number

91/d/130/575

Health conditions studied**1****Description of health condition studied**

Hemodialysis patient

ICD-10 code

Z49.1

ICD-10 code description

Extracorporeal dialysis

Primary outcomes**1****Description**

Ventilation of hemodialysis patients

Timepoint

Before the intervention, after a month and two months after

Method of measurement

Spirometer

Secondary outcomes**1****Description**

The distance traveled in 6 minutes by the patient

Timepoint

Ago, one month and two months after intervention

Method of measurement

6 minutes walk test

Intervention groups**1****Description**

In the intervention group, patients during two months, every day to 3-5 times, each time three times in 5 minutes on the training of researchers will use the incentive spirometer. the patient is taught that mouthpiece of the device to put in your mouth, perform inhalation with maximum, imprisonment breath to for 3 seconds, then exhalation with pressure. Using Spirometry guide as a pamphlet give to experimental group participants.

Category

Rehabilitation

2**Description**

Control group receive routine hospital

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Hasheminezhad hospital
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical science, research dputy
Full name of responsible person
Dr. Akbar Fotohi
Street address
tehran, keshavarz blvd., ghods st., ghods bld.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical science, research dputy
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

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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