

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6693 7120

##### Email address

aliasgha@sina.tums.ac.ir

##### 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

**Name of organization / entity**  
Tehran University of Medical science  
**Full name of responsible person**  
Mansoor ali asgharpour  
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Educator  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*