

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Sep 2026

### The effect of training the usage of inhaler with and without spacer on pulmonary function and skill of inhaler application in patient with asthma referring to selected clinics of shiraz university of medical science

#### Protocol summary

##### Summary

Objective: this study is a randomized clinical trial on 90 patients with asthma in selected clinics in Shiraz (Faghihi and Motahary) was performed to evaluate the effect of training the usage of inhaler with and without spacer on pulmonary function and skill of inhaler application in patient with asthma. Design: after obtaining informed consent, eligible patients were randomly assigned to three groups: group inhalation technique with spacer; group of inhalation technique without spacer and control. Methods: we measured the peak expiratory flow rate with peak flow meter before and after inhalation of salbutamol 200 micrograms, as a basic test in the three groups, and also skill of inhaler application were evaluated with inhalation technique checklist in three groups. In the next step three educational sessions were held. In spacer group were taught how to use inhaler with spacer and in without spacer group were taught how to use inhaler without spacer. The control group received no intervention. Then lung test and skill of inhaler application was measured immediately and one month after education. Inclusion criteria: being in the age range 60-18 years old; the use of salbutamol production in Sina Daru Company for at least three months; not to participate in a similar training program. Exclusion criteria: smoking; patient unwillingness to continue cooperation; Asthma Attack. Intervention: teaching correct use of spray with spacer and Teaching correct use of spray without spacer.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013091514666N1**

Registration date: **2013-11-23, 1392/09/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-11-23, 1392/09/02

##### Registrant information

###### Name

Fatemeh Ansarfard

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 72 2446 3290

###### Email address

ansarfard\_f@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

##### Expected recruitment start date

2013-04-21, 1392/02/01

##### Expected recruitment end date

2013-06-20, 1392/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of training the usage of inhaler with and without spacer on pulmonary function and skill of inhaler application in patient with asthma referring to selected clinics of shiraz university of medical science

**Public title**

The effect of training the usage of inhaler with and without spacer on pulmonary function and skill of inhaler application in patient with asthma

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: Asthma diagnosed by a physician; age between 18-60 years old; willingness to participate in research; physical ability to usage spray; access to telephone to follow-up program by the researcher; use of salbutamol spray at least three months; not affected by heart disease, pneumonia, pneumothorax, and other systemic diseases; not participated in a similar training program; ability reading and writing (at least at the basic level of education) and understand Persian. Exclusion criteria: absence in training sessions; unwillingness to continue or discontinue patient cooperation in the during of study for any reason; asthma attack; smoking; change the treatment plan.

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

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

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Shiraz University of Medical Sciences Ethics Committee

**Street address**

7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Fars Province, Iran, 1978 -71345

**City**

shiraz

**Postal code**

71345-1978

**Approval date**

2010-09-23, 1389/07/01

**Ethics committee reference number**

6675

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

Asthma

**ICD-10 code**

J45

**ICD-10 code description**

Asthma

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

Peak expiratory flow rate

**Timepoint**

Before education, immediately and one month after education

**Method of measurement**

Peak flow meter

**2****Description**

skill of inhaler application

**Timepoint**

Before education, immediately and one month after education

**Method of measurement**

inhalation technique check list

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

Adverse effects after inhalation of drug

**Timepoint**

Before education, immediately and one month after education

**Method of measurement**

Observation

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

intervention1: spacer group were trained the correct use of inhaler with spacer. First session was about recognition of symptoms of asthma, including definition, etiology and drug treatment .Second session was about emphasis on importance of correct use of spray with spacer and advantages of using spacer for patients and

its positive impact on the treatment process Also patients were taught correct use of inhaler with spacer Practically . and Third Session was about Summary of inhalation technique with spacer, review and eliminate pitfall of inhalation technique.

#### Category

Prevention

### 2

#### Description

intervention 2: without spacer group: were trained the correct use of inhaler without spacer First session was about recognition of symptoms of asthma, including definition, etiology and drug treatment .Second session was about emphasis on importance of correct use of spray for patients and its positive impact on the treatment process Also patients were taught correct use of inhaler without spacer Practically . and Third Session was about Summary of inhalation technique, review and eliminate pitfall of inhalation technique.

#### Category

Treatment - Drugs

### 3

#### Description

intervention3: The control group received no intervention. Finally the both types of inhalation technique were presented to the patients through pamphlets

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faghihi and Motahari clinics

##### Full name of responsible person

Dr moham Ali Ghayomi

##### Street address

Sixth floor, Motahari clinic, Shiraz

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Shiraz University of Medical Sciences

##### Full name of responsible person

Dr. Gholamreza Hatam

##### Street address

7th floor, Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Fars Province

##### City

Shiraz

#### 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, Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Mr. Hashem Rahmati

##### Position

Master of nursing

##### Other areas of specialty/work

##### Street address

Hazrat-e-Fatemeh nursing and midwifery college, Namazi Hospital, Namazi Square, Shiraz.

##### City

Shiraz

##### Postal code

71345-1978

##### Phone

+98 71 1647 4254

##### Fax

+98 71 1627 9135

##### Email

h\_rahmati@yahoo.com

##### Web page address

www.sums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Hashem Rahmati

##### Position

Master of nursing

##### Other areas of specialty/work

##### Street address

Hazrat-e-Fatemeh nursing and midwifery college, Namazi Hospital, Namazi Square, Shiraz.

##### City

Shiraz  
**Postal code**  
71345-1978  
**Phone**  
+98 71 1647 4254  
**Fax**  
+98 71 1627 9135  
**Email**  
H-Ramati1076@yahoo.com  
**Web page address**  
www.sums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Ansarfard Fatemeh  
**Position**  
Master student of nursig  
**Other areas of specialty/work**  
**Street address**  
Hazrat-e-Fatemeh nursing and midwifery college,  
Namazi Hospital, Namazi Square, Shiraz.  
**City**

Shiraz  
**Postal code**  
**Phone**  
**Fax**  
+98 71 1212 2430  
**Email**  
ansarfard\_f@sums.ac.ir; fatemeh102@yahoo.com  
**Web page address**  
www.sums.ac.ir

## 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*