

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

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Name of organization / entity

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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

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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

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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

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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