

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of using corticosteroids metered dose inhaler with or without spacer in patients without coordination problems with uncontrolled or poorly controlled asthma, a randomized clinical trial

Protocol summary

Study aim

To evaluate the effectiveness of adding spacer to inhaled corticosteroid (ICS) in improving asthma control in patients with uncontrolled or poorly controlled asthma

Design

The patient will be asked about the spray usage and the days of forgetting the ICS, and patients with proper adherence will be included in the study. The validated Asthma control test score is calculated for the patient, and if the score is less than 20, the patient is interviewed to enter the study, and then an informed consent form is obtained. Relevant demographic information, spirometry, patient medications, other diseases will be recorded. Patients are randomly assigned to one of two spacer or control groups.

Settings and conduct

All patients with asthma referred to the Pulmonary Clinic of Imam Khomeini Hospital will be examined. The attending physician will be blinded in this study (single blind).

Participants/Inclusion and exclusion criteria

Inclusion: 1. Adults over 18 to 65 years old with uncontrolled or poorly controlled asthma (ACT score < 20) 2. Using corticosteroid inhaler in the form of MDI (metered dose inhaler) for at least three months before starting the study. Exclusion: 1. tremors, Parkinson's or using medications that cause tremors 2. Neuro-cognitive problems that lead to incorrect use of the spray by the patient. 3. Non-adherence to medication 4. Dissatisfaction 5.. Having a critical error when using inhalation spray

Intervention groups

1. Spacer group: A free of cost spacer is given to the patient to connect it to his/her corticosteroid inhaler to take the medicine with the spacer. Other treatments of the patient will be unchanged. 2. Control group: The patient's treatment will continue according to the

doctor's opinion and without a spacer.

Main outcome variables

Asthma control test questionnaire score Forced vital capacity (FVC) forced expiratory volume in 1 second (FEV1) FEV1/FVC ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230731058982N1**
Registration date: **2023-08-12, 1402/05/21**
Registration timing: **prospective**

Last update: **2023-08-12, 1402/05/21**

Update count: **0**

Registration date

2023-08-12, 1402/05/21

Registrant information

Name

Niloofer Khoshnam-Rad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6119 2644

Email address

kh.niloofer@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-21, 1402/05/30

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of using corticosteroids metered dose inhaler with or without spacer in patients without coordination problems with uncontrolled or poorly controlled asthma, a randomized clinical trial

Public title

Comparison of using corticosteroids metered dose inhaler with or without spacer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adults over 18 to 65 years old with uncontrolled or poorly controlled asthma (ACT score < 20) Using corticosteroid inhalers in the form of MDI (metered dose inhaler) for at least three months before starting the study and being adherent to treatments Not Having a critical error when using inhalation spray

Exclusion criteria:

Suffering from any tremors, Parkinson's, or using medications that cause tremors continuously Neuro-cognitive problems that lead to incorrect use of the inhaler by the patient. Not consented to include in the trial

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

First, each patient is given a number from 1 to 114 with a computerized random number generation algorithm. These numbers are placed randomly in two spacer or control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the use of spacers in this study, the included patients will not be blinded to the intervention. The attending physician in this study will be blinded to the treatment of his patient in terms of receiving or not receiving a spacer. This means that the patient will be referred to the principal investigator, and then receive treatment according to the randomized group. Data analyzer will be blind to group assignment of patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

Street address

Thoracic Research Center, Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2023-07-31, 1402/05/09

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.166

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

Asthma

ICD-10 code

J45

ICD-10 code description

Asthma

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

Asthma Control Test (ACT)

Timepoint

Six weeks

Method of measurement

Asthma Control Test questionnaire

2**Description**

Spirometry indexes including FEV1, FVC, FEV1/FVC

Timepoint

before intervention and 6 weeks after intervention

Method of measurement

Spirometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Spacer group: A free-of-cost spacer is given to the patient to attach it to his corticosteroid spray, and take his ICS with the spacer for six weeks from the intervention time. Other treatments for the patient will be as before. The spacer is a plastic piece that is connected to the inhalation spray. Patients use corticosteroid inhalation (ICS) spray twice a day, which will be used twice a day for six weeks with a spacer in this group

Category

Treatment - Devices

2

Description

Control group: In this group, the patient will take his corticosteroid inhalation spray (ICS) twice a day without adding a spacer as prescribed by the doctor.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeinin Hospital

Full name of responsible person

Besharat Rahimi

Street address

Thoracic Research Center, Imam Khomeini Hospital Complex, Tohid Squire,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Niloofar Khoshnam-Rad

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Thoracic Research Center, Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

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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

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Niloofar Khoshnam-Rad

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

No - There is not a plan to make this available