Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Niloofar Khoshnam-Rad
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 6119 2644
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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 Squre, 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

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

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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 Squre, 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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Position
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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