Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Clinical trial of recovery rate comparison in patients with unexplained chronic cough in the two groups receiving oral cetirizine with and without inhaled budesonide.

Protocol summary

Summary

We are trying to assess therapeutic effect of inhaled budesonide in patients with unexplained chronic cough. In this triple-blind clinical trial, 68 patients with chronic cough (more than 8 weeks) who referred to outpatient pulmonary disease clinic will be visited by experienced pulmonologist. After refused to recognize the causes of disease, the forced oscillation technique (FOT), fractional exhaled nitric oxide (FENO) and inhaled methacholine challenge test (MCT) as a provocation test is performed. By a trained interviewer all cases with negative MCT informed about the study. Cases will be entre to the study, will be perform FOT and will be complete the information in check lists if accept to sign the written satisfaction. Block randomization will be used to enter cases to each group. Turbuhalers will be lot into two groups (A or B), also encoded by a table of random numbers. All patients according to the protocol of the Center for Drug, Cetirizine 10 milligram daily plus a coded turbuhaler and educated for correct consumption (2 puffs every 12 hours). After 25 days of treatment, patients will be visited by pulmonologist again, and FOT, FENO will be done and will be interviewed to complete the needed information.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031212419N2**
Registration date: **2017-11-19, 1396/08/28**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name
Mehrnaz Asadi Gharabaghi
Name of organization / entity
Tehran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

The cost of the study will be provided by the researchers.

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of recovery rate comparison in patients with unexplained chronic cough in the two groups receiving oral cetirizine with and without inhaled budesonide.

Public title

The therapeutic effect of inhaled budesonide in patients with unexplained chronic cough.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age over 18 years; unexplained chronic

cough for more than 8 weeks; absence of underling cardiac diseases; do not using smoking and drugs; absence of clinical and para-clinical asthma evidence; normal chest x-ray; normal spirometry; absence of eosinophilic bronchitis (sputum eosinophil percentage less than 3%); negative (normal) inhaled methacholine provocation test; signed written consent; absence of pregnancy and breast feeding; did not taking steroids during the last 3 months; do not receive any treatment for chronic cough before and during study; do not taking Angiotensin converting enzyme inhibitors (ACEI). Exclusion criteria: dissatisfaction to continuing cooperation in each stage of the study; exacerbation or other accidents which requiring treatment; lack of returning within 48 hours of the deadline for second visit.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

After obtaining relevant permissions from the University, patients with a chronic cough (more than 8 weeks), are considered as potential cases of entry into the study. They will be visited by experienced pulmonologist as the routine; sinusitis and gastroesophageal reflux based on history and physical examination and other documents will be refused. Then standard Chest radiography (Posteroanterior and Lateral view), spirometry and the smear of sputum smear analysis for eosinophil's percentage. Will be done. Those who have normal spirometry and chest radiography and sputum eosinophil percentage is less than 3%, referred for further evaluation. For these patients, the Forced Oscillation Technique (FOT) and (FENO) Fractional Exhaled Nitric Oxide and inhaled methacholine provocation challenge test (MCT) will be done. At this point, who with normal MCT will be selected and the project will be present. The benefits and consequences of treatment used and the running way they completely explained. Cases will be entre to the study, will be performed FOT and will be complete the information in checklists if accept to sign the written satisfaction. Block randomization will be used to enter cases to each group and will be interviewed by a trained interviewer to question questionnaire Numeric Cough Quality Score (NCS), Visual analog scale (VAS) and other information as needed to study and complete in the Check - List for each patient. In case of need defects in the information will be completed by the interviewer during the study in pursuit of the phone. Turbuhalers will be a lottery into two groups (A or B), also encoded by a table of random numbers. All patients according to the protocol of the Center for Drug, Cetirizine 10 (Letizen®) milligram daily plus a coded Turbuhaler and educated for correct consumption (2 puffs every 12 hours). Turbuhalers will be labeled only by numeric codes without any distinguishable symptom from others. After 25 days of treatment, patients will be visited by pulmonologist again, and FOT, FENO will be done and will be interviewed to complete the needed information. Then patients discharge from study to continue their treatment process. This process till the completion of the sample size will continue. Obtained information in the checklists will be analyzed by in SPSS 23 software. During the analysis first, numerical codes replaced by letters (A/B) for each Turbuhaler and after analysis in the results letter codes will be replaced by drug or placebo group. So Code information will be sealed and maintained until the final analysis away from patients, researchers, interviewer, and analyzer to blind the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences - Imam Khomeini Hospital

Street address

Imam Khomeini Hospital, End of Keshavarz Blv.

City

Tehran

Postal code

1419733141

Approval date

2017-03-28, 1396/01/08

Ethics committee reference number

IR.TUMS.IKHC.REC.1396.2002

Health conditions studied

1

Description of health condition studied

unexplained chronic cough

ICD-10 code

R05

ICD-10 code description

Cough

Primary outcomes

1

Description
Budesonide inhalation treatment response in Numeric Cough Score questionnaire.
Timepoint
Before intervention and a day after it.
Method of measurement
Questionnaire

2

Description
Budesonide inhalation treatment response in visual analogue scale score.
Timepoint
Before intervention and a day after it.
Method of measurement
Questionnaire

Secondary outcomes

1

Description
Budesonide inhalation treatment response with Forced Oscillation Technique spirometry parameters.
Timepoint
Before intervention in two periods; before and after methacholine challenge test and a day after intervention.
Method of measurement
Forced Oscillation Technique spirometry

2

Description
Budesonide inhalation treatment response with Fractional Exhaled Nitric Oxide.
Timepoint
Before intervention and the day after it.
Method of measurement
Fractional Exhaled Nitric Oxide test

Intervention groups

1

Description
Intervention group or Intervene 1: Treatment will be done by cetirizine (letizen®) 10 milligram oral daily plus inhale budesonide Turbuhaler 200 microgram 2 puff every 12 hours for 25 days.
Category
Treatment - Drugs

2

Description
Control group or Intervene 2: Treatment will be done by cetirizine (letizen®) 10 milligram oral daily plus Turbuhaler without effective drug (placebo) 2 puff every 12 hours for 25 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pulmonary disease clinic
Full name of responsible person
Mehrnaz Asadi Gharabaghi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The budget will be funded by researchers.
Full name of responsible person
Mehrnaz Asadi Gharabaghi
Street address
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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
The budget will be funded by researchers.
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 Sciences
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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