Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 2026

Effects of sodium cromoglycate on lung function tests in asthmitc subejects without exposure to any bronchoconstrictor trigger

Protocol summary

Summary

This is a pilot study on effects of cromolyn on asthmatic subjects in Tehran, which is a randomized double-blind and placebo-controlled clinical trial. Among asthmatic patients who referring to Department of Internal Medicine of Imam-Khomeini Hospital, 40 patients with a documented diagnosis of bronchial asthma with a FEV1 < 80% of predicted value, and reversible airflow obstruction which are in a stable condition, enter to the study. Exclusion criteria include acute asthma attack, smoking, respiratory tract infections within 1 month of the study (according to history and physical examination) and presence of chronic diseases such as heart disease. After announcement of study, volunteers would be attended the laboratory at two days. In the day one, firstly for ethic consideration, the consent would be obtained in writing from each volunteer after that a brief explanation of trial including efficacy and safety of drug in asthma was given. Then subjects were instructed on how to perform spirometric test and on the technique for inhaling sodium cromolyn through the spinhaler, by an expert technician. Also, method of antiasthma drug discontinuation would be ordered to patient, by a physician as following: β2-adrenoceptor agonist would be withheld for 6h before the study, methylxanthines and cromolyn would be withheld for 24 h, and aerosol steroids would be withheld on the morning of the study day.Thereafter, patient would be entered by random allocation to the following groups: inhalation of cromolyn-20mg, inhalation of cromolyn-40mg or inhalation of cromolyn-placebo In the second day (two days later), on arrival at the laboratory after a rest time, the subject would perform three lung function maneuvers. The best value would be taken as baseline spirometry. Then for determining effect of cromolyn, lung function tests would be repeated at 15, 30 and 60 minutes after inhalation. Then at each time, percent of improvement in important lung function variables, such as forced expiratory volume in one second (FEV1) from baseline values would be calculated and compared between three groups. One hour after the last test, patient will be observed for any adverse effect of drug

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804222118N1**
Registration date: **2011-07-10, 1390/04/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-07-10, 1390/04/19

Registrant information

Name
Tajemah Mombeini
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Recruitment status

Recruitment complete

Funding source

RESEARCH DEPEUTY, SHAHED UNIVERSITY

Expected recruitment start date

2011-06-02, 1390/03/12

Expected recruitment end date

2011-08-02, 1390/05/11

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of sodium cromoglycate on lung function tests in asthmitc subejects without exposure to any bronchoconstrictor trigger

Public title
Effects of cromolyn sodium on lung function in asthmatic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion critreia: subjects with documented diagnosis of asthma and reversible airflow obstruction; FEV1<80% of predicted value;in a stable condition with regard to asthma symptoms Exclusion criteria: acute attack of asthma; chronic disease such as heart disease; pateints with respiratory infection in last month; smoking
Age
From **27 years** old to **57 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ETHIC COMMITTEE of SHAHED UNIVERSITY
Street address
RESEARCH DEPEUTY, SHAHED UNIVERSITY, AGAINST IMAM-KHOMEINI HARAM, FIRST OF TEHRAN-GHOAM HIGHWAY, TEHRAN, IRAN
City
TEHRAN
Postal code

Approval date
2011-06-01, 1390/03/11
Ethics committee reference number
112437

Health conditions studied

1

Description of health condition studied
bronchial asthma
ICD-10 code
j45
ICD-10 code description
Predominantly allergic asthma

Primary outcomes

1

Description
FEV1
Timepoint
15 min, 30 min, 60min after inhalation
Method of measurement
Spirometry test

2

Description
FVC
Timepoint
15min, 30min, 60min after inhalation
Method of measurement
spirometry test

3

Description
PEF
Timepoint
15 min, 30 min, 60min after inhalation
Method of measurement
Spirometry test

4

Description
MEF25%
Timepoint
15 min, 30 min, 60min after inhalation
Method of measurement
Spirometry test

5

Description
MEF50%
Timepoint
15 min, 30 min, 60min after inhalation
Method of measurement
Spirometry test

6

Description
MEF75%
Timepoint
15 min, 30 min, 60min after inhalation
Method of measurement
Spirometry test

Secondary outcomes

1

Description
Adverse effects after inhalation of drug or placebo
Timepoint
each 15 min after inhalation, until 2 hours
Method of measurement
observation

Intervention groups

1

Description
1. cromolyn 20 group: Patient must inhale powder content of a capsule of cromolyn sodium (20 mg) by spinhaler through mouth.
Category
Treatment - Drugs

2

Description
2. cromolyn 40 group: Patient must inhale 40mg powder of cromolyn sodium by spinhaler through mouth.
Category
Treatment - Drugs

3

Description
3. placebo group:Patient must inhale from a hollow and cleaned (dose not contain any drug) capsule of cromolyn sodium by spinhaler through mouth.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
IMAM-KHOMEINI HOSPITAL
Full name of responsible person
DR TAJEMAH MOMBEINI
Street address
DEPARTMENT OF INTERNAL MEDICINE, IMAM-KHOMEINI HOSPITAL, DR GHARIB ST, KESHAVARZ BLVD, TEHRAN
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Sponsors / Funding sources

1

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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
RESEARCH DEPEUTY, SHAHED UNIVERSITY
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
SCHOOL OF MEDICINE, SHAHED UNIVERSITY
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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