Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jul 2019

Effect of inhaled Cromolyn on cough of mild persistent asthma in resistant patients to inhaled Corticosteroid and antileukotriene, A double blind randomized clinical trial.

Protocol summary

Summary
Objectives: The objective of this study is to determine the effect of cromolyn to standard therapy in mild persistent resistant to corticosteroid and anti leukotriene Asthma with normal Spirometry. Design: Prospective randomized controlled clinical trial (active comparator study). Setting and conduct: A pulmonary subspecialty clinic. Participants including major eligibility criteria: Sixty two asthmatic subjects with mild persistent corticosteroid and anti leukotriene resistant Asthma. Subjects suffering from other underlying diseases such as respiratory infection, sever or moderate Asthma, Rhinosinositis, Gastro-Oesophageal Reflux, other obstructive lung disease, vocal cord dysfunction, and reactive airway dysfunction syndrome will be excluded from study. After randomization eligible subjects will receive cromolyn or placebo. Independent pharmacists dispensed either Cromolyn or Placebo according to a computer generated randomization list. Intervention: Each cromolyn or placebo will be consumed for forty days, correct usage of spray and spacer will be educated to patients. After this period they will be evaluated for main parameters. Main outcome (variables) includes: change of clinical finding, change of Spirometry, change of Sputum cytology include inflammatory cell, change of ACT (Asthma control test) Questionnaire and change of FENO (Fractional Exhaled Nitric Oxide). These parameters will be evaluated again after completing the course of treatment.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT201108042695N3
Registration date: 2014-04-13, 1393/01/24
Registration timing: retrospective

Last update: empty
Update count: 0
Registration date
2014-04-13, 1393/01/24

Registraiton information
Name
Majid Mirsadraee
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Recruitment status
Recruitment complete
Funding source
Mashhad branch-Islamic Azad University

Expected recruitment start date
2012-09-28, 1391/07/07
Expected recruitment end date
2013-12-19, 1392/09/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of inhaled Cromolyn on cough of mild persistent asthma in resistant patients to inhaled Corticosteroid and antileukotriene, A double blind randomized clinical trial.

Public title
Effect of inhaled Cromolyn on persistent asthma

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: cough with an intermittent course and history of airway hyper responsiveness; FEV1(Forced Expiratory volume in 1 second) more than 80% (mild asthma); No beneficial effect of inhaled Corticosteroid anti leukotriene during previous treatment. Exclusion criteria: Moderate or severe asthma; FEV1 (Forced Expiratory volume in 1 second) less than 80%; Asthma...
with wheezing; Respiratory infection; Treatment with systemic Corticosteroid; Other Obstructive lung disease; Rhinosinositis; Gastro-esophageal Reflux; Vocal Cord Dysfunction; Reactive airway dysfunction syndrome.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
None

Sample size
Target sample size: 62

Randomization (investigator's opinion)
Randomized

Randomization description
Double blinded

Blinding (investigator's opinion)
Double blinded

Placebo
Used

Assignment
Parallel

Other design features
Due to spontaneous remission of asthma and long term period of treatment with cromolyn double blind randomized clinical trial was used as the best method of study. All recruited asthmatic subjects will randomly divided to two groups of cromolyn inhaler and placebo by computer generated randomization list. One group will be treated by cromolyn or and other group will be received placebo for forty days. Both of them will use spray and the dosage will be 2 puff four times. The physician and pharmacist are blind to the exact drug which the subject will be started with. The cromolyn and placebo form is spray and identical in appearance. They have consecutively numbered for each patient according to the randomization schedule which is not introduced to the physician and pharmacist.

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Mashhad branchbranch-Islamic Azad University-Ethical committee- Department of research

Street address
Shahin Far Building- Sarab Street- Azadi street

city
Mashhad

Country
Iran (Islamic Republic of)

Postal code
9178673799

Approval date
2011-04-24, 1390/02/04

Ethics committee reference number
A56-21

Health conditions studied

1

Description of health condition studied
Asthma

ICD-10 code
J45.32

ICD-10 code description
Mild Persistent Asthma, Status asthmaticus

Primary outcomes

1

Description
Change of FENO (Fractional Exhaled Nitric Oxide)

Timepoint
Before treatment and 40 days after treatment

Method of measurement

2

Description
Change of FEV1 (Forced Expiratory volume in 1 second)

Timepoint
Before treatment and 40 days after treatment

Method of measurement

3

Description
Change of Sputum Cytology

Timepoint
Before treatment and 40 days after treatment

Method of measurement
Sputum Cytology for frequency of inflammatory cell (Eosinophil, Neutrophil, Macrophage and Lymphocyte) defined by percentage calculated into 200 cell in each high power field Microscopic in magnification 40x in Sputum.

Secondary outcomes

1

Description
Change of IL-8

Timepoint
One year later

Method of measurement
Enzyme-linked immunosorbent assay (ELISA)
Description

1. **Chenge of INF- GAMMA**
   - **Timepoint**: One year later
   - **Method of measurement**: Enzyme-linked immunosorbent assay (ELISA)

3. **Chenge of IL-17**
   - **Timepoint**: One year later
   - **Method of measurement**: Enzyme-linked immunosorbent assay (ELISA)

4. **Chenge of TLR-2**
   - **Timepoint**: One year later
   - **Method of measurement**: Enzyme-linked immunosorbent assay (ELISA)

### Intervention groups

1. **Description**
   - Steps before starting the study: Asthmatic subjects referred with cough and history of recurrence with or without reactive airway hyper responsiveness and without wheezing will be treated with one puff spray fluticasone 250 twice a day with spacer. Spacer usage will be educated. If they do not improve after one week oral Montelukast will be added to previous drug. Afterward chest x ray will be taken, if they do not improve again. In case of infiltration in favor of infection, they will cure with Doxycycline 100 mg or clarythromycin 500 mg two twice a day for 10 days. In subjects with normal chest X ray anti reflux therapy will be added to previous drugs including Fluticason and montelukast. Patients whom do not improve with these regimens will be entered to our study. Phase one: Recruitment of subjects: Asthmatic subjects referred with cough and history of recurrence with or without reactive airway hyper responsiveness and without wheezing will be treated with one puff spray fluticasone 250 twice a day with spacer. spacer usage will be educated. If they do not improve after one week oral Montelukast will be added to previous drug. Afterward chest x ray will be taken, if they do not improve again. In case of infiltration in favor of infection, they will cure with Doxycycline 100 mg or clarythromycin 500 mg two twice a day for 10 days. In subjects with normal chest X ray anti reflux therapy will be added to previous drugs including Fluticason and montelukast. Patients whom do not improve with these regimens will be entered to our study. Phase one: Recruitment of subjects: Asthmatic subjects referred with cough and history of recurrence with or without reactive airway hyper responsiveness and without wheezing will be treated with one puff spray fluticasone 250 twice a day with spacer. spacer usage will be educated. If they do not improve after one week oral Montelukast will be added to previous drug. Afterward chest x ray will be taken, if they do not improve again. In case of infiltration in favor of infection, they will cure with Doxycycline 100 mg or clarythromycin 500 mg two twice a day for 10 days. In subjects with normal chest X ray anti reflux therapy will be added to previous drugs including Fluticason and montelukast. Patients whom do not improve with these regimens will be entered to our study.

### Recruitment centers

1. **Recruitment center**
   - **Name of recruitment center**: Mashhad branch-Islamic Azad University
   - **Full name of responsible person**: Mojtaba Meshkat
   - **Street address**: Shahin Farr building, Sarab street, Azadi Avenue
   - **City**: Mashhad
   - **Country**: Iran (Islamic Republic of)

### Sponsors / Funding sources

1. **Sponsor**
   - **Name of organization / entity**: Mashhad Branch-Islamic Azad University
   - **Full name of responsible person**: Mojtaba Meshkat
   - **Street address**: Shahin Farr building, Sarab street, Azadi avenue
   - **City**: Mashhad
   - **Country**: Iran (Islamic Republic of)

- **Grant name**
- **Grant code / Reference number**
- **Is the source of funding the same sponsor organization/entity?**
  - Yes
- **Title of funding source**
Mashhad Branch-Islamic Azad 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**
empty

**Type of organization providing the funding**
empty

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**Person responsible for general inquiries**

**Contact**

- **Name of organization / entity**
  Mashhad Branch-Islamic Azad University

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- **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