Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Investigation and comparison of the efficacy and side effects of only nebulized oral Pulmicort and only inhaled budesonide and diet with oral budesonide nebul in patients aged one to 18 years with eosinophilic esophagitis

Protocol summary

Study aim

Comparison of eosinophilia and clinical symptoms improvement in children with eosinophilic esophagitis in three groups: oral budesonide nebulization intervention, inhaled budesonide spry and non-drug diet regimen, and follow-up of local and systemic side effects.

Design

A randomized, double blinded clinical trial study with community-based and pragmatic control group, and parallel groups

Settings and conduct

After patient's selection based on inclusion and exclusion criteria, the basic results of endoscopic, histopathological examination, eosinophil count, as well as routine hematological and biochemical tests will be measured. Patients will be randomly divided into three intervention groups of nebulized oral pulmicort, inhaler budesonide and diet without drug. At the beginning of the study and after the end of week 16th, patients in all groups will be referred again to the center for endoscopy by a specialist physician and will be examined histologically and histologically, as well as eosinophil counts and cortisol examination at 8 am o'clock.

Participants/Inclusion and exclusion criteria

Only patients 1 to 18 years of age with eosinophilic esophagitis will be included in the study. Children with a history of systemic disease, adrenal insufficiency, other congenital or genetic defects, and a history of systemic corticosteroid medications will be excluded from the study.

Intervention groups

only oral budesonide nebul group only inhaled budesonide spray group mixed food elimination plus oral nebul

Main outcome variables

The important outcome of the current survey is the effect of nebulized oral pulmicort, inhaler budesonide and diet without drug for improving of eosinophilic esophagitis which is performed by measuring several factors such as eosinophil counts, as well as endoscopic and histopathological examinations.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191211045703N1**
Registration date: **2020-06-24, 1399/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-24, 1399/04/04**
Update count: **0**

Registration date

2020-06-24, 1399/04/04

Registrant information

Name

Nastaran Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date
2020-09-05, 1399/06/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation and comparison of the efficacy and side effects of only nebulized oral Pulmicort and only inhaled budesonide and diet with oral budesonide nebul in patients aged one to 18 years with eosinophilic esophagitis

Public title
Comparison of the efficay and side effects of nebulized oral pulmicort and inhaler budesonide in patients with eosinophilic esophagitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pediatric patients with eosinophilic esophagitis consent form parents proton pump consumption Adherence to the treatment protocols of this study
Exclusion criteria:
history of systemic corticosteroids drugs using history of systemic underlying diseases Adrenal insufficiency history
Age
From **1 year** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
For this purpose, the random allocation law method was used. In random allocation (based on probability principles) eliminates the link between intervention and potential distortion.Random allocation was used by variable block method.The randomization unit was individual.In this way, a set of 60 cards was prepared, which included three 20-block blocks of three types of cards A, B, and C, which were randomly and randomly removed for each person by the researcher. The collection could not be returned.
Blinding (investigator's opinion)
Double blinded
Blinding description
Due to the fact that this study did not have a placebo and the drug form used was completely different. Only the data analyst did not know which group the recorded clinical information belonged to.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Zafar Street, Ali Asghar Hospital
City
tehran
Province
Tehran
Postal code
1919816366
Approval date
2019-11-26, 1398/09/05
Ethics committee reference number
IR.IUMS.FMD.REC.1398.371

Health conditions studied

1

Description of health condition studied
eosinophilic esophagitis
ICD-10 code
K20.0
ICD-10 code description
Eosinophilic esophagitis

Primary outcomes

1

Description
The effect of oral Budesonide nebulizer on improving Eosinophilic Esophagitis.
Timepoint
Patients in the oral Budesonide nebulizer group will receive 1 puff twice a day.If the effectiveness of the drug is not observed after 8 weeks, patients will receive 2 puffs twice a day.Then during weeks 4,12,8 and 16 patients will be followed up and examined.
Method of measurement
At the beginning of the study and after the 16th week, patients will be re-examined for histological and tissue pathology, as well as blood eosinophil counts and cortisol examination by Enzyme-linked immunosorbent test at 8 a.m.There will also be a routine laboratory test, such as hematology and biochemistry.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: nebulized oral pulmicort.Palmicortic is a drug containing budesonide and belongs to the corticosteroids, which are commonly used to reduce and prevent inflammation and swelling in the lungs and asthma.The drug is manufactured by ASTRAZENECA from Sweden. Patients in pulmicort group less than 20 kg will receive 0.5 mg/dose/day, while those over 20 kg will receive 1 mg/dose/day for 8 weeks. In case there is no improvement in the disease after 8 weeks, patients fewer than 20 kg will receive 1mg/dose/day and those over 20 kg will receive 2 mg/dose/day. Patients will be followed-up on the 4th, 8th, 12th, and 16th weeks.
Category
Treatment - Drugs

2

Description
Intervention group: inhaler budesonide.An inhaled drug containing budesonide belongs to the corticosteroids, which are commonly used to reduce and prevent inflammation and swelling in the lungs and asthma. Each prescription contains 2 ml of sterile solution.This solution must be turned into steam for inhalation in a special device.Patients in the budesonide spray group will receive 1 puff twice daily. In case no efficacy is observed, patients will receive 2 puffs twice daily for 8 weeks. Patients will then be monitored and evaluated on 4th, 8th, 12th and 16th weeks.
Category
Treatment - Drugs

3

Description
Control group: diet without drug. In this group patients will not receive any type of drug intervention.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat-e Rasul Hospital
Full name of responsible person
Nastarn Amiri
Street address
Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Ave,Tehran,Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Morteza Fallah pour
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Nastaran Amiri
Position
رزیدنت اطفال

Latest degree
Medical doctor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Documents and information of demographic data, clinical and pathological findings of all patients will be shared, but personal data are will not be shared.
When the data will become available and for how long
At the end of study and after publication of article
To whom data/document is available
University researchers physicians pharmacologists
Under which criteria data/document could be used
Medical researcher can use data after getting admission from all members of this study for further research
From where data/document is obtainable
They should contact with Dr. Nastaran Amiri
What processes are involved for a request to access data/document
They should initially contact with Dr. Nastaran Amiri to get permission
Comments