

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

evaluation of efficacy of synbiotics in resolution of symptoms , pathologic and endoscopic findings in children with eosinophilic esophagitis

Protocol summary

Study aim

evaluation of efficacy of synbiotics in resolution of symptoms, pathologic and endoscopic findings in children with eosinophilic esophagitis

Design

A randomized, controlled, placebo-controlled clinical trial

Settings and conduct

The study will be carried out on 40 patients with eosinophilic esophagitis referred to Imam Hossein Hospital in Isfahan, Iran. These children are patients who present with suspected symptoms such as Stomach ache, vomiting, regurgitation, weight loss disorder, dysphagia, and undergo endoscopy and biopsy for definitive diagnosis by a gastroenterologist. Depending on clinical signs and pathologic findings, including the presence of at least 15 eosinophils per HPF, a definitive diagnosis of the disease will be made for these children. Patients will be randomly divided into control and intervention groups of 20 each. Information is provided to the statistician after being anonymized.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient's consent to participate in the study, their eosinophilic esophagitis diagnosed and confirmed by endoscopy, patients age 6 months to 15 years. Exclusion criteria: use of other medications which may affect the recovery of the disease.

Intervention groups

Both groups will be pre-treated for at least 8 weeks with omeprazole at a dose of 1 mg daily, the same diet, Nutrition education (to parents), and topical steroids, such as fluticasone spray and budesonide. Intervention (n = 20) Patients will receive Cynical Lock (Iranian) synbiotic with two daily doses for 8 weeks and the intervention group (n = 20) will receive the same dose and placebo.

Main outcome variables

clinical symptoms, pathological findings, endoscopic status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171230038142N14**

Registration date: **2020-03-11, 1398/12/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-11, 1398/12/21**

Update count: **0**

Registration date

2020-03-11, 1398/12/21

Registrant information

Name

Khosro Tavakol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 9134

Email address

tavakol@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of efficacy of synbiotics in resolution of symptoms , pathologic and endoscopic findings in children with eosinophilic esophagitis

Public title

evaluation of efficacy of synbiotics in children with eosinophilic esophagitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patient parental consent to participate in the study
Eosinophilic esophagitis is diagnosed and confirmed by endoscopy Patients age 6 months to 15 years

Exclusion criteria:

Use of other medicines that can improve the disease.

Age

From **6 months** old to **15 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to the control and intervention groups using the envelope in which the letters (c) stands for control group and the letter (i) stands for intervention group. Initially, 20 envelopes with the letter c and 20 envelopes with the letter i will be considered and, after being selected by the child or their parent, the child's name will be written on it.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hazar Jarib Street

City

Esfahan

Province

Isfahan

Postal code

81746-73461

Approval date

2019-10-14, 1398/07/22

Ethics committee reference number

IR.MUI.MED.REC.1398.365

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**

clinical symptoms

Timepoint

Before and eight weeks after intervention

Method of measurement

Examination by a pediatrician

2**Description**

Pathologic findings

Timepoint

Before and eight weeks after intervention

Method of measurement

Gastric biopsy and eosinophil count by microscope

3**Description**

Endoscopic findings

Timepoint

Before and eight weeks after intervention

Method of measurement

Endoscopy in hospital by pediatric gastroenterologist

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: They will be treated for at least 8 weeks with omeprazole (Iranian from Abidi Pharmacy) at a dose of 1 mg / kg, daily, also under appropriate diet (given nutritional training to parents). And topical steroids will include fluticasone spray and budesonide.

Then, 20 patients will receive Cidetabic Synthetic Intervention (from Iranian Bio-Fermentation Pharmaceutical Company) with two daily doses for 8 weeks.

Category

Treatment - Drugs

2**Description**

Control group: They will be treated with at least 1 mg / kg once daily for at least 8 weeks of omeprazole (Iranian from Abidi Pharmacy). And topical steroids will include fluticasone spray and budesonide. Then 20 placebo control group will be given two daily doses for 8 weeks.

Category

Diagnosis

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hussein Hospital

Full name of responsible person

Niloufar Zamani

Street address

Imam Khomeini street

City

Esfahan

Province

Isfahan

Postal code

8195163381

Phone

+98 31 3386 6266

Fax**Email**

emamhossein_hospital@mui.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Ziba Farajzadegan

Street address

Vice-Chancellor for Research of School of Medicine, .
Isfahan University of Medical Sciences, . Hezar Jarib
Ave.

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dean@med.mui.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Niloufar Zamani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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gebrahimi676@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Niloufar Zamani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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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

The information is available to physicians and pediatricians two years after the results are published.

When the data will become available and for how long

Two years after the results were published

To whom data/document is available

physicians and pediatricians

Under which criteria data/document could be used

Compare current treatment with other treatment

From where data/document is obtainable

Request permission from Isfahan Medical School Research Assistant and send an email to gebrahimi676@gmail.com and request.

What processes are involved for a request to access data/document

Request permission from Isfahan Medical School Research Assistant and send an email to gebrahimi676@gmail.com and request.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Niloufar Zamani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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