Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
Isfehan
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

Isfehan

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.

City

Isfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3668 8597

Email

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

Street address

Isfahan University of Medical Sciences, Hazar Jarib Street

City

Esfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3668 8597

Fax

+98 31 3668 8597

Email

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
Street address
Isfahan University of Medical Sciences, Hazar Jarib Street
City
Esfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 8597
Fax
+98 31 3668 8597
Email
gebrahimi676@gmail.com

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
Street address
Isfahan University of Medical Sciences, Hazar Jarib Street
City
Esfahan
Province
Isfehan
Postal code
81746-73461
Phone
+98 31 3668 8597
Fax
+98 31 3668 8597
Email
gebrahimi676@gmail.com

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