Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial study in treatment of children with gastroesophageal reflux disease symptoms: Cydonia oblonga syrup versus omeprazole syrup

Protocol summary

Summary

This is an outpatient, double-blind and randomized clinical trial study to compare the effects of Cydonia oblonga syrup with Omeprazole syrup in children aged 1 months to 18 years old with symptomatic gastroesophageal reflux disease. 80 patients after getting informed consent signed by the parent / guardian, will be accepted. They are according to the instructions North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition for gastroesophageal reflux disease and supervision of a pediatric gastroenterologist, will be selected. They will allocate to two arms using block randomization. Drugs will be encoded and prescribe 2 times a day for 4 weeks. Patients will evaluating by the age specific questionnaire for gastroesophageal reflux disease symptoms for 7 weeks (2 weeks post-treatment).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030921388N1**
Registration date: **2015-05-16, 1394/02/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-05-16, 1394/02/26

Registrant information

Name
Mohammad Ebrahim Zohalinezhad
Name of organization / entity
Shiraz University of Medical scineces
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Shiraz university of medical sciences

Expected recruitment start date

2015-02-09, 1393/11/20

Expected recruitment end date

2015-05-10, 1394/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial study in treatment of children with gastroesophageal reflux disease symptoms: Cydonia oblonga syrup versus omeprazole syrup

Public title

The evaluation of effectiveness of "Cydonia oblonga syrup" on clinical symptoms in patients with Gastroesophageal reflux disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children more than one month and less than 18 years old; signed an informed consent form by parents; Vomiting immediately after eating; restlessness for one to three hours after feeding; respiratory distress after feeding; the lack of weight gain; refusing to eat; endoscopically proven gasteroeshophageal reflux disease. Exclusion criteria: Children younger than 1 month and older than 18 years old; those who need to use other oral or intravenous drugs; unwillingness to

continue to participate in the study; sensitivity to study drugs; patients with other gasteroeshophageal disorders such as esophagitis and peptic ulcer; patients with active renal, liver and neurological diseases; mental retardation; pregnancy; lactation and disability of parents/guardian to cooperate in filling the forms (cognitive or language disorder).

Age
From **1 month** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Zand Ave.

City
Shiraz

Postal code

Approval date
2015-02-08, 1393/11/19

Ethics committee reference number
CT-9370-7360

Health conditions studied

1

Description of health condition studied
Pediatric gastro-oesophageal reflux disease

ICD-10 code
K21.9

ICD-10 code description
Gastro-oesophageal reflux disease without oesophagitis

Primary outcomes

1

Description
Vomiting/regurgitation episodes

Timepoint
Weekly

Method of measurement
Age specific gastroesophageal reflux disease questionnaire

2

Description
Severity of Vomiting/regurgitation

Timepoint
Weekly

Method of measurement
Age specific gastroesophageal reflux disease questionnaire

3

Description
Refusal of feed episodes

Timepoint
Weekly

Method of measurement
Age specific gastroesophageal reflux disease questionnaire

4

Description
Severity of feed refusal

Timepoint
Weekly

Method of measurement
Age specific gastroesophageal reflux disease questionnaire

5

Description
Irritability/Fussiness episodes

Timepoint
Weekly

Method of measurement
Age specific gastroesophageal reflux disease questionnaire

6

Description
Severity of Irritability/Fussiness

Timepoint
Weekly

Method of measurement
Age specific gastroesophageal reflux disease questionnaire

7

Description
Hiccup/Belching episodes
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

8

Description
Severity of hiccup/belching
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

9

Description
Choking when eating episodes
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

10

Description
Severity of Choking when eating
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

11

Description
Arching back episodes
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

12

Description
Severity of arching back
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

13

Description
Abdominal pain episodes
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

14

Description
Severity of abdominal pain
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

15

Description
Nausea episodes
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

16

Description
Severity of nausea
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

17

Description
Chest pain/ Heart burn episodes
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

18

Description
Severity of chest pain/ heart burn
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

19

Description
Difficulty swallowing episodes
Timepoint
Weekly
Method of measurement

Age specific gastroesophageal reflux disease questionnaire

20

Description
Severity of difficulty swallowing
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

21

Description
Pain after eating episodes
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

22

Description
Severity of pain after eating
Timepoint
Weekly
Method of measurement
Age specific gastroesophageal reflux disease questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Omeprazole syrup, 1.5 mg\kg\day, oral, twice a day, 4 weeks
Category
Treatment - Drugs

2

Description
Cydonia oblonga syrup, 1.5 g\kg\day, oral, twice a day, 4 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza (PUBH) clinic, Shiraz University of Medical Scineces
Full name of responsible person
Dr. Zohalinezhad
Street address
Iranian Traditional Medicine College, Medicine Faculty, Imam Hossein Square, Zand Street
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Hashemi
Street address
Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences, Zand Street.
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
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
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Person responsible for scientific inquiries

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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