

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 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 sciences

Country

Iran (Islamic Republic of)

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+98 71 3233 7589

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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 gastroesophageal 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 gastroesophageal 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 Sciences

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

Shiraz University of Medical Sciences

Full name of responsible person

Zohalinezhad

Position

M.D./PhD candidate of Traditional Medicine

Other areas of specialty/work

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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