

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effect of abdominal massage with Mastic gum oil on the symptoms of gastroesophageal reflux disease in children 2month-1year compared to abdominal massage without oil.

Protocol summary

Study aim

-Comparison of the effect of abdominal massage with and without mastic gum oil on the severity and frequency of vomiting, crying and restlessness while breastfeeding of Gastroesophageal reflux disease in children from 2 months to 1 years. - Comparison of the effect of abdominal massage with and without mastic gum oil on the Symptoms recurrence of Gastroesophageal reflux disease in children from 2 months to 1 years.

Design

Clinical trials with community-based and pragmatic control group, with parallel groups, without blindness, randomized

Settings and conduct

Listed 90 patients with gastro-oesophageal reflux who have entered the research criteria from the Hazrat Ali Asghar Hospital GSQ-I questionnaire completed and randomly divided into 2 groups of 45 people

Participants/Inclusion and exclusion criteria

Children aged 2 months to 1 year referred to the clinic of Ali Asghar Hospital Diagnosis of GERD according to GSQ-I questionnaire and Pediatric gastroenterologist Not having other serious gastrointestinal diseases, such as esophagitis, achalasia, gastrointestinal ulcers, inflammatory diseases of the gastrointestinal tract, etc. According to the pediatric gastroenterologist .History of allergy or skin allergy to the drug or herbal compounds Allergy to cow's milk protein

Intervention groups

Intervention group is received omeprazole capsules and abdominal masage with mastic gum oil. Omeprazole (Abidi®) will be prescribed 1 mg/kg/day in 2 divided Dose, 15 min before child feedingAbdominal massage is performed 10-15 minutes every 12 hours, half an hour after eating milk or auxiliary food, The treatment will last for two weeks. The control group will receive omeprazole

capsules and abdominal massage without oil.

Main outcome variables

Severity and frequency of vomiting, crying and restlessness, during the last 7 days,Recurrence symptoms one week and 4 weeks after treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180406039204N1**

Registration date: **2018-05-16, 1397/02/26**

Registration timing: **registered_while_recruiting**

Last update: **2018-05-16, 1397/02/26**

Update count: **0**

Registration date

2018-05-16, 1397/02/26

Registrant information

Name

Mansureh Akhavan

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-10, 1397/02/20

Expected recruitment end date

2019-05-10, 1398/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of abdominal massage with Mastic gum oil on the symptoms of gastroesophageal reflux disease in children 2month-1year compared to abdominal massage without oil.

Public title

Evaluation the effect of abdominal massage with Mastic gum oil on the reflux disease in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children more than two months and less than 1 years old in aliasghar hospital Diagnosis of GERD on the basis of GSQ-I questionnaire and pediatric gastroenterologist Absence of serious gastrointestinal diseases such as esophagitis, achalasia, gastrointestinal ulcers, IBD (Inflammatory Bowel disease),....

Exclusion criteria:

History of allergy or skin allergy to the drug or herbal compounds Allergy to cow's milk protein Infants with a history of gastrointestinal surgery and neurological disease, liver, kidney, or history of severe cardio-pulmonary disease, as well as history of peptic ulcer Guardian to cooperate in filling the forms (cognitive or language disorder).

AgeFrom **2 months** old to **1 year** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

Block randomization Based on random numbers

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The abdominal massage is performed rotated and clockwise

Secondary Ids

empty

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

Ethics committee of Iran University of Medical Sciences

Street address

Fifth Floor, Headquarters, Hemet Highway Between Chamran and Sheikh Fazlullah, Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2018-02-25, 1396/12/06

Ethics committee reference number

IR.IUMS.REC1396.9421309001

Health conditions studied**1****Description of health condition studied**

Gastroesophageal reflux

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes**1****Description**

Severity of css index

Timepoint

At the beginning of the study, 14 days after the intervention and 7, 28 days after discontinuation of treatment

Method of measurement

GSQ-I questionnaire

2**Description**

Severity and frequency of vomiting

Timepoint

At the beginning of the study, 14 days after the intervention and 7, 28 days after discontinuation of treatment

Method of measurement

GSQ-I questionnaire

3**Description**

Severity and frequency of crying and restlessness while

breastfeeding

Timepoint

At the beginning of the study, 14 days after the intervention and 7, 28 days after discontinuation of treatment

Method of measurement

GSQ-I questionnaire

Secondary outcomes

1

Description

side effect

Timepoint

Any time during the study

Method of measurement

Report by the child's supervisor

2

Description

Time Control Signs

Timepoint

Any time during the study

Method of measurement

Report by the child's supervisor

3

Description

Recurrence of symptoms

Timepoint

7 and 28 days after discontinuation of treatment

Method of measurement

Report by the child's supervisor

Intervention groups

1

Description

Intervention group: Omeprazole capsule and abdominal massage with mastic gum oil. Omeprazole (Abidi®) will be prescribed 1 mg/kg/day in 1 Dose, Fasting morning before child feeding. Abdominal massage with mastic gum oil every 12 hours, half an hour after milking or supplements. Duration of treatment is 2 weeks

Category

Treatment - Drugs

2

Description

Control group: Omeprazole capsule and abdominal massage without oil. Omeprazole (Abidi®) will be prescribed 1 mg/kg/day in 1 Dose, Fasting morning before child feeding. Abdominal massage every 12 hours, half an hour after milking or supplements. Duration of treatment is 2 weeks

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Hospital

Full name of responsible person

mansooreh akhavan

Street address

Ali Asghar Hospital ,zafar street.shariati street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

50

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

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Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

mansooreh akhavan

Position

Iranian medical resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Latest degree

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Person responsible for updating data

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Full name of responsible person

mansureh akhavan

Position

Iranian medical resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

Street address

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available