

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparative study of the effect of abdominal massage with rose oil and olive oil on the symptoms of Gastroesophageal reflux disease in pediatrics

Protocol summary

Study aim

Comparative study of the effect of abdominal massage with rose oil and olive oil on the symptoms of Gastroesophageal reflux disease in pediatrics aged 2 months to 1 year

Design

Two arm parallel group triple-blind randomized clinical trial

Settings and conduct

Patients are divided into two groups. For the first group, in addition to the usual treatment, abdominal massage with rose oil in the base of olive oil (every 12 hours) and for the second group, in addition to routine treatment, abdominal massage with olive oil (every 12 hours) is prescribed. Patients will be monitored weekly for the effect of the drug on clinical symptoms and its possible complications.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Children 2 months to 1 year referred to Ali Asghar Hospital Clinic Diagnosis of GERD based on GSQ-I questionnaire by pediatric gastroenterologist
Exclusion criteria: Serious gastrointestinal diseases such as esophagitis, achalasia, gastrointestinal ulcers, inflammatory gastrointestinal diseases A history of allergy to herbal ingredients Allergy to cow milk protein History of gastrointestinal surgery History of liver, kidney, neurologic or severe cardiopulmonary diseases Inability of parents to cooperate in filling out the forms (mental disorders or language problems)

Intervention groups

90 patients with gastroesophageal reflux who meet the inclusion criteria are selected and divided into two groups randomly. For the first group, in addition to the usual treatment, abdominal massage with Rose oil at the base of the olive oil (every 12 hours), and for the second group, in addition to the usual treatment, abdominal massage with olive oil (every 12 hours) is prescribed. The effects and complications of drug will be monitored weekly.

Main outcome variables

Vomiting; Crying and restlessness during breast feeding; Side effects; Symptom control time; Symptom recurrence

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191216045752N1**

Registration date: **2020-01-28, 1398/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2020-01-28, 1398/11/08**

Update count: **0**

Registration date

2020-01-28, 1398/11/08

Registrant information

Name

maryam moghimi

Name of organization / entity

Masiha Teb Shomal Knowledge-based cooperation

Country

Iran (Islamic Republic of)

Phone

+98 21 6676 5787

Email address

baran10mordad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of abdominal massage with rose oil and olive oil on the symptoms of Gastroesophageal reflux disease in pediatrics

Public title

Comparative study of the effect of abdominal massage with rose oil and olive oil on the symptoms of Gastroesophageal reflux disease in pediatrics

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children 2 months to 1 year referred to Ali Asghar Hospital Clinic Diagnosis of GERD based on GSQ-I questionnaire by pediatric gastroenterologist

Exclusion criteria:

serious gastrointestinal diseases such as esophagitis, achalasia, gastrointestinal ulcers, inflammatory gastrointestinal diseases A history of allergy to herbal ingredients Allergy to cow milk protein History of gastrointestinal surgery History of liver, kidney, neurologic or severe cardiopulmonary diseases Inability of parents to cooperate in filling out the forms (mental disorders or language problems)

Age

From **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

The presenter divides the participants into two groups according to the severity of the disease and refers them to the secretary of the ward. Two series of randomized blocks for severely and moderately ill patients are already provided to the secretary, in which letters A and B are written in unspecified sequences. Depending on the severity of the disease, the secretary selects one of these groups for the patient and gives him/her the appropriate drug. The drugs, which are almost similar in color and smell, are packed in 60cc containers and given to the secretary who is unaware of the contents of the container.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The presenter divides the participants into two groups according to the severity of the disease and refers them to the secretary of the ward. Two series of randomized blocks for severely and moderately ill patients are

already provided to the secretary, in which letters A and B are written in unspecified sequences. Depending on the severity of the disease, the secretary selects one of these groups for the patient and gives him/her the appropriate drug. The drugs, which are almost similar in color and smell, are packed in 60cc containers and given to the secretary who is unaware of the contents of the container.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Iran university of medical sciences

Street address

Hemat highway, next to Milad tower

City

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1449614535

Approval date

2019-11-04, 1398/08/13

Ethics committee reference number

IR.lums.rec.1398.799

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

gastroesophageal reflux (GERD)

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The intensity and frequency of vomiting during the past 7 days

Timepoint

Weeks 1, 2, 3 and 4 during the intervention and weeks 1 and 4 after the intervention

Method of measurement

Asking parents

2

Description

Time to control symptoms

Timepoint

Weeks 1, 2, 3 and 4 during the intervention and weeks 1 and 4 after the intervention

Method of measurement

Asking parents

Secondary outcomes

1

Description

Crying and restlessness while breastfeeding

Timepoint

Weeks 1, 2, 3 and 4 during the intervention and weeks 1 and 4 after the intervention

Method of measurement

Asking parents

2

Description

side effects

Timepoint

Weeks 1, 2, 3 and 4 during the intervention and weeks 1 and 4 after the intervention

Method of measurement

Asking parents

Intervention groups

1

Description

Intervention group: Infants from 2 months to 1 year of age with gastroesophageal reflux of the first group, in addition to the usual treatment, are given an abdominal massage with rose oil (in the base of olive oil) every 12 hours. For greater effectiveness, a topical abdominal massaging method is chosen, with 1-5 drops per 10-15 minutes based on birth months.

Category

Treatment - Drugs

2

Description

Intervention group: Infants from 2 months to 1 year of age with gastroesophageal reflux of the second group, in addition to the usual treatment, are given an abdominal massage with olive oil every 12 hours. For greater effectiveness, a topical abdominal massaging method is chosen, with 1-5 drops per 10-15 minutes based on birth months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar hospital

Full name of responsible person

Hoorieh mohammadi kenari

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Vahid Dastgerdi Ave., Modarres highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Institute for Islamic and Complementary Medicine

Full name of responsible person

Amir Hosein Jamshidi

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No.748, Behesht street, Vahdat eslami Ave., Hasan Abad Sq.

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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

Research Institute for Islamic and Complementary Medicine

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

Research Institute for Islamic and Complementary
Medicine

Full name of responsible person

Hoorieh mohammadi Kenari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Masiha Teb Shomal Knowledge-based cooperation

Full name of responsible person

Maryam Moghimi

Position

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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

This will be mentioned in the article method.

When the data will become available and for how long

This will be mentioned in the article method.

To whom data/document is available

This will be mentioned in the article method.

Under which criteria data/document could be used

This will be mentioned in the article method.

From where data/document is obtainable

This will be mentioned in the article method.

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

This will be mentioned in the article method.

Comments