

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effectiveness of drug and non-drug treatment through group training on esophageal reflux control in children 12 months to 3 years

Protocol summary

Study aim

Determining the comparison of the effectiveness of drug and non-drug treatment through group training on the control of esophageal reflux in children

Design

Sampling will be done with a sequential non-probability method. With a control group, with parallel groups, the samples will be randomly divided into two test groups (N=56) and control (N=56) using the randomized permutation method.

Settings and conduct

The research sample includes 112 infants aged 12 months to 3 years with esophageal reflux. The research environment is teaching hospitals affiliated to Ahvaz University of Medical Sciences. In the test group (56 people), the educational intervention will be implemented in a combined form (face-to-face and showing an educational film approved by the doctor and presenting a pamphlet) by the researcher during 6 45-minute sessions (one session per week). For the control group, no educational intervention will be done.

Participants/Inclusion and exclusion criteria

1- Having a child with esophageal reflux 2. Child age between 12 months and 3 years. 3- Not having a history of uncontrolled underlying disease 4- Parents have the ability to receive education (at least elementary literacy level) 5- lack of parents participating in the previous class
non criteria: 1. Children below 12 months and above three years. 2. Lack of proficiency in Persian language.

Intervention groups

For the test group, the educational intervention will be conducted in a combined form (face-to-face and showing an educational film approved by the doctor and presentation of a pamphlet) by the researcher during 6 45-minute sessions (one session per week). No educational intervention will be done for the control group.

Main outcome variables

The Level of control of esophageal reflux in children

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221104056396N1**

Registration date: **2023-01-25, 1401/11/05**

Registration timing: **prospective**

Last update: **2023-01-25, 1401/11/05**

Update count: **0**

Registration date

2023-01-25, 1401/11/05

Registrant information

Name

Ashraf Al sadat Hakim

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 61 3311 2392

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hakim3448200@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-05, 1401/11/16

Expected recruitment end date

2023-05-08, 1402/02/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effectiveness of drug and non-drug treatment through group training on esophageal reflux control in children 12 months to 3 years

Public title
Investigating the effect of group training on the control of esophageal reflux in children

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
 Having a child with esophageal reflux. Child age between 12 months and 3 years Not having a history of uncontrolled underlying disease parents have the ability to receive education (at least elementary literacy level) Lack of parents' participation in the previous class
Exclusion criteria:
 Children below 12 months and above three years Lack of proficiency in Persian language

Age
From **12 months** old to **3 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **112**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples were first selected from among the research community based on the inclusion criteria. The random assignment of the research sample to two intervention and control groups will be done based on quadruple permutation blocks (using the table related to random permutation blocks, of Twenty-eight groups of four). In this method, the number of people assigned to each group is almost equal. Blocks are formed based on the variables in question, and half of the intervention people and half of the control people are included in each block. The main goal is to balance the number of participants in each group. is

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Jundishapur University of Medical Sciences, Ahvaz

Street address

Golestan Boulevard. Esfand Street, University of Medical Sciences

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2022-10-03, 1401/07/11

Ethics committee reference number

IR.AJUMS.REC.1401.271

Health conditions studied

1

Description of health condition studied

Esophageal reflux

ICD-10 code

K21

ICD-10 code description

Gastro-esophageal reflux disease

Primary outcomes

1

Description

Esophageal reflux

Timepoint

Before the start of the intervention and two months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the non-pharmacological treatment group, in order to educate the parents, educational sessions will be held in the form of group discussions, during which the parents will be divided into groups of 5-6 people. And the side effects, the child's nutrition and position, and physical and emotional needs will be carried out by the researcher during 6 sessions of 45 minutes (one session per week), and at the end of the training sessions, an educational pamphlet will be provided to them.

Category
Behavior

2

Description

In the control group, no educational intervention will be done: the medical treatment of esomeprazole tablets is prescribed by the doctor, once a day for 6 months. However, in order to comply with ethical considerations, after analyzing the results, the educational pamphlet will be delivered to the control group.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Abu Dhar Hospital

Full name of responsible person

Ashrafalsadat Hakim

Street address

Ahvaz Zaytoon Karmani. Pasdaran Blvd. Nurse Street.
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2

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Deputy of research and technology- Dr. Mehrnoosh
Zakerkish

Street address

Ahvaz Golestan Boulevard. Esfand St. Jundishapur
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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ashrafalsadat Hakim

Position

Assistant professor, faculty member

Latest degree

Master

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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