

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Effect of appliance of dietary interventions based on Persian medicine by nursing mothers on infantile gastroesophageal reflux.

Protocol summary

Study aim

Investigation of the effect of appliance of dietary interventions based on Persian medicine by nursing mothers on infantile gastroesophageal reflux

Design

In this research, 84 eligible patients referring to Persian Medicine Center of Shahed University or Aliasghar subspecialty hospital for children were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

Center of Study: Persian Medicine Center of Shahed University and Aliasghar subspecialty hospital for children; Method Of Study: In first clinical visit mothers of intervention group will receive dietary interventions based on Persian Medicine which breastmilk correction is gold concept, also lifestyle modification about infantile GER will be taught to both intervention and control group, these interventions must apply for 4 weeks, then at the end of 2nd week (through phone contact), the end of 4th week (through clinical visit) and the end of 6th week (through phone contact) frequency and severity of signs and symptoms of reflux will be assessed; in this study all interventions will be secret from mothers of both groups and appointment days will separate for participant of each group

Participants/Inclusion and exclusion criteria

Inclusion criteria : Infants under 5 months old with mild to moderate infantile GER which the diagnosis is confirmed by the pediatric gastroenterologist; Exclusion criteria: Any significant medical or surgical disease of mother or infant; Necessity of medical treatment for infantile GER at the beginning or duration of the study; Other types of gastrointestinal diseases such as esophagitis, peptic ulcer ,etc

Intervention groups

Intervention group: In first clinical visit mothers will receive dietary interventions which is based on Persian

Medicine, also in order to keep the infants from being absent of classical medicine treatment mothers is being taught about infantile reflux lifestyle modification;
Control group: In first clinical visit in order to keep the infants from being absent of classical medicine treatment mothers is being taught about infantile reflux lifestyle modification

Main outcome variables

Assessment and comparison of frequency of signs and symptoms of infantile GER in both groups: in 2nd, 4th and 6th week; Assessment and comparison of severity of signs and symptoms of infantile GER in both groups: in 2nd, 4th and 6th week;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170701034828N1**
Registration date: **2017-12-28, 1396/10/07**
Registration timing: **registered_while_recruiting**

Last update: **2017-12-28, 1396/10/07**

Update count: **0**

Registration date

2017-12-28, 1396/10/07

Registrant information

Name

Maryam Jahangir

Name of organization / entity

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Recruitment status**Recruitment complete****Funding source**

Vice chancellor for research, Shahed University

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of appliance of dietary interventions based on Persian medicine by nursing mothers on infantile gastroesophageal reflux.

Public title

Effect of dietary interventions based on Persian medicine on infantile gastroesophageal reflux.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infants under 5 months old (girls and boys) Exclusive breastfeeding Clinically confirmation of infantile GER by the pediatric gastroenterologist Score of Gastroesophageal Reflux Questionnaire - Infantile (GSQ-I questionnaire) above 16 (the min score for confirm GER)

Exclusion criteria:

Any diagnosed disease of mother or infant that needs medical or surgical therapy Any other type of gastrointestinal disease such as hiatal hernia, erosive esophagitis, etc in infants Necessity of medical treatment for infantile reflux at the beginning or through the study Any diagnosed disease of mother or infant that due to it breastfeeding is forbidden Any consumption of effective medicine on GER in infants, such as Proton pump inhibitors, H2-receptor antagonists, etc

Age

To 5 months old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 84

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method is permuted block randomization. Each unit of randomization is a person.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a single blind trial, which participants are not aware of the two intervention methods.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shahed University, Ethics Committee on Biomedical Research

Street address

Shahed University, Front of Imam Khomeini holy shrine, Persian Gulf freeway (Tehran-Qom), Tehran

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3319118651

Approval date

2017-08-27, 1396/06/05

Ethics committee reference number

IR.Shahed.REC.1396.30

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

Infantile Gastroesophageal Reflux

ICD-10 code

P78.8

ICD-10 code description

Other specified perinatal digestive system disorders

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

Frequency of Infantile Gastroesophageal Reflux signs

Timepoint

Before intervention, 2 weeks after intervention, the end of intervention (4th week), 6th week

Method of measurement

GERD Symptoms Questionnaire for infants (GSQ-I)

2**Description**

Severity of Infantile Gastroesophageal Reflux signs

Timepoint

Before intervention, 2 weeks after intervention, the end of intervention (4th week), 6th week

Method of measurement

GERD Symptoms Questionnaire for infants (GSQ-I)

Secondary outcomes

1

Description

Infant weight

Timepoint

Before intervention, The end of intervention (4th week)

Method of measurement

Baby scale, Gramme

2

Description

Infant height

Timepoint

Before intervention, The end of intervention (4th week)

Method of measurement

Measuring board, centimeter

3

Description

Nursing mothers' gastric temperament

Timepoint

Before intervention, The end of intervention (4th week)

Method of measurement

Gastric temperament check list

Intervention groups

1

Description

Intervention 1 (Intervention Group) : Dietary interventions based on Persian medicine will be presented to nursing mothers of this group in 1 session (1st clinical visit) as face to face teaching by executor of plan, and the written guidance paper will be

Category

Lifestyle

2

Description

Intervention 2 (Control Group): Classic medicine's standard treatment strategy of mild to moderate infantile GERD which is about lifestyle modifications and breastfeeding pattern, will be presented to control group. So these infants are not being deprived

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center of Iranian Traditional Medicine of shahed University

Full name of responsible person

Maryam Jahangir

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Shahid Jafari Alley, 3rd Dashtestan Alley, lower than Hosseiniye-e-ershad, Shariati st, Tehran

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahed University

Full name of responsible person

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 http://shahed.ac.ir/research/Pages/Home.aspx
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Vice chancellor for research, Shahed University
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

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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

Not applicable