

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Sep 2026

Efficacy of Hypoallergenic diet and administration of Ranitidine in treatment of Gastroesophageal reflux disease in infants one month to one years old

Protocol summary

Summary

The purpose of this study is to compare the effects of a hypoallergenic diet, and ranitidine administration in treating infants (1-12 months) with gastroesophageal reflux. Infants with vomiting or those with regurgitation plus one of the following symptoms: irritability, insufficient weight gain and respiratory distress will be enrolled in this study. Anyone with obstructive diseases, kidney diseases, central nervous system diseases (CNS), severe respiratory symptoms such as cyanosis, apnea, or respiratory distress will be excluded from the study. Patients are selected from infants who are referred to the Isfahan University of Medical Sciences Clinics. A sample size of 50 was calculated and patients will be randomly allocated in two groups to receive ranitidine or follow a hypoallergenic diet. For two weeks, those in the ranitidine group will receive 10 mg/kg of ranitidine daily divided into 2 doses, and in the diet group, all allergens are eliminated from the mother's diet. At the end of the two weeks, frequency and volume of vomiting, irritability, weight gain, respiratory symptoms and arching will be compared before and after intervention between the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042714882N3**
Registration date: **2016-02-16, 1394/11/27**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-16, 1394/11/27

Registrant information

Name

Fatemeh Famouri

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Science

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2015-01-30, 1393/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Hypoallergenic diet and administration of Ranitidine in treatment of Gastroesophageal reflux disease in infants one month to one years old

Public title

Efficacy of Hypoallergenic diet on infant's reflux

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1 month to 1 year infants with vomiting or regurgitation plus one of following symptoms,

Irritability; Insufficient weight gain; Respiratory symptoms. Exclusion criteria: Renal disease; urinary tract infection(UTI); CNS (Central nerves system); Respiratory symptoms; Apnea; Cyanosis; Respiratory distress.

Age
From **1 month** old to **1 year** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Randomization of patients into two treatment groups will be done using lottery cards. Twenty-five pairs of cards, each of which has a letter A or B (based on its designated treatment method) are placed inside a container, and the patients' parents are requested to take a card from that container. Based on the card's letter, each patient will be assigned to one of the treatment groups. This process continues until all patients are assigned to a group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan, Isfahan University of Medical Sciences

City

Isfahan

Postal code

81746-73461

Approval date

2014-08-27, 1393/06/05

Ethics committee reference number

393605

Health conditions studied

1

Description of health condition studied

Gastroesophageal reflux

ICD-10 code

K21.9

ICD-10 code description

Gastro-oesophageal reflux disease without oesophagitis(Oesophageal reflux NOS)

Primary outcomes

1

Description

Frequency of vomiting per day

Timepoint

Two weeks after intervention

Method of measurement

Counting the episode of vomiting per day. Asking question from mothers and recording in questionnaire

2

Description

Volume of vomiting

Timepoint

Two weeks after intervention

Method of measurement

Asking question from mother about volume of vomiting and recording in questionnaire

Secondary outcomes

1

Description

Irritability severity

Timepoint

Two weeks after intervention

Method of measurement

Asking question from mothers and recording in questionnaire

2

Description

Weight gain

Timepoint

Two weeks after intervention

Method of measurement

Weighing patient

3

Description

Respiratory symptoms

Timepoint

Two weeks after intervention

Method of measurement

Asking question from mothers and recording in questionnaire

4

Description

Arching

Timepoint

Two weeks after intervention

Method of measurement

Asking question from mothers and recording in questionnaire

Intervention groups

1

Description

The treatment group will be eliminate allergens from mother's diet for 2 weeks. Hypoallergenic diet was defined, diet free of milk and dairy products, cow's meat, peanut, fish and soy.

Category

Lifestyle

2

Description

The Ranitidine consumer group will receive Ranitidine 10 mg per kg per day divided to 2 doses for 2 week. (Ranitidine syrup 15 mg per ml, Alhavi Pharmaceutical Company)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein(A) Hospital

Full name of responsible person

Dr. Fatemeh Famouri

Street address

Emam Hossein(A) Hospital, Isfahan, Iran

City

Isfahan

2

Recruitment center

Name of recruitment center

Out Patient Academic Clinic of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Famouri

Street address

Sepahsalar Street, Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Dr Mansour Siavash

Street address

Isfahan University of Medical Sciences, Isfahan, Iran

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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

Vice chancellor for research, Isfahan 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

Child Growth and Development Center and Pediatric Group of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Nazanin Zibanejad

Position

Pediatric Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Group of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Fatemeh Famouri

Position

Assistant Professor, Gastrointestinal and Hepatology
Subspecialist

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Full name of responsible person

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Professor/Pediatrician

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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