

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3663 7291

###### Email address

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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

**City**

Isfahan

**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

**City**

Isfahan

**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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**Contact**

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

**Full name of responsible person**

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**Position**

Assistant Professor, Gastrointestinal and Hepatology  
Subspecialist

**Other areas of specialty/work**

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

**Full name of responsible person**

Dr. Roya Kelishadi

**Position**

Professor/Pediatrician

**Other areas of specialty/work**

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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*