

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Comparison of the effect of treatment with omeprazole and es-omeprazole in reflux disease (GERD) infants Lesser than one year old

#### Protocol summary

##### Study aim

The effect of omeprazole and es-omeprazole on infants under one year old with reflux disease

##### Design

Clinical trial with control group, with parallel group, double-blind, non-randomized groups

##### Settings and conduct

All infants under one year of age referred to gastrointestinal clinics of Kashan city in year 1398 will receive reflux disease based on medical history and clinical examination and will be prescribed omeprazole and es-omeprazole for their treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : 1) Infants 1 to 11 months of age with clinical diagnosis of GERD based on symptoms or endoscopic evidence. Exclusion criteria: 1) Using a PPI in the last 7 days. 2) Treatment for reflux symptoms, including histamine 2 receptor antagonists, prokinetics, and bismuth-containing antacids within 24 hours before intervention. 3) Patients with active gastrointestinal bleeding, apnea, allergic gastroenteritis, eosinophilic gastroenteritis, bleeding disorders, pyloric stenosis, active seizure disorder, acute pancreatitis or meningitis.

##### Intervention groups

Omeprazole and S-omeprazole 0.25 mg / kg in infants under one year with reflux inclusion criteria for 4 weeks.

##### Main outcome variables

Age Sex Weight Measuring time Intervention group Recovery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191027045256N1**

Registration date: **2020-03-09, 1398/12/19**

Registration timing: **retrospective**

Last update: **2020-03-09, 1398/12/19**

Update count: **0**

##### Registration date

2020-03-09, 1398/12/19

##### Registrant information

###### Name

Mohamad Ali Sabahi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 25 3291 7528

###### Email address

alisabahi1369@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-10-07, 1398/07/15

##### Expected recruitment end date

2019-11-16, 1398/08/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of treatment with omeprazole and es-omeprazole in reflux disease (GERD) infants Lesser than one year old

##### Public title

effect of omeprazole and es-omeprazole in reflux disease

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Infants 1 to 11 months of age with clinical diagnosis of reflux based on symptoms or endoscopic evidence

**Exclusion criteria:**

Using a PPI in the last 7 days Treatment for reflux symptoms, including histamine 2 receptor antagonists, prokinetics, and bismuth-containing antacids within 24 hours before intervention Patients with active gastrointestinal bleeding, apnea, allergic gastroenteritis, eosinophilic gastroenteritis, bleeding disorders, pyloric stenosis, active seizure disorder, acute pancreatitis or meningitis

**Age**

From **1 month** old to **11 months** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients will be randomly assigned to receive an oral dose of these two drugs at random for four weeks, in which participants, parents, caregivers, researchers, and pharmacists will be blinded to treatment.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

**Street address**

Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan

**City**

Kashan

**Province**

Isfahan

**Postal code**

87159-81151

**Approval date**

2019-10-06, 1398/07/14

**Ethics committee reference number**

IR.KAUMS.REC1398037

**Health conditions studied**

1

**Description of health condition studied**

GERD

**ICD-10 code**

K21.9

**ICD-10 code description**

Gastro-esophageal reflux disease without esophagitis

**Primary outcomes**

1

**Description**

Effect of Omeprazole and S-Omeprazole in Children

**Timepoint**

Symptoms evaluated included vomiting, contractility, irritability, hyper-esophageal and respiratory disorders (eg cough, wheezing / steroids) and nutritional problems (eg, dizziness / choking). 1 hour will be defined. Vomiting / regurgitation volume will be classified as small (5-15 ml), medium (15-30 ml), large (more than 30 ml) at any time of 4 weeks.

**Method of measurement**

Recovery involves reducing the severity of symptoms to more than half of the initial symptom score (before the intervention).

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Intervention group 1: Esomeprazole Abidi company,

**Category**

Treatment - Drugs

2

**Description**

Intervention group 1: eprazole Abidi company

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Shahid Beheshti hospital

**Full name of responsible person**

Seyed Ramin Madani

**Street address**

Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan

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**Postal code**

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**Phone**

+98 31 5557 8010

**Email**

alisabahi1369@gmail.com

**Web page address****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Mohamadali Sabahi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Pediatrics

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

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**Email**

drraminmadani@gmail.com

**Web page address****Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kashan 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Seyed Ramin Madani

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

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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**

No more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable