

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 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

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Kashan university of medical sciences, Qotbe Ravandi Blvd, Kashan

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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**

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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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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Other areas of specialty/work

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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