

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Comparison of omeprazole and ranitidine in treatment of symptomatic gastroesophageal reflux disease in infants 2 -12 months old

Protocol summary

Summary

Children aged 2-12 months with symptomatic gastroesophageal reflux disease (GERD) were recruited to randomized, parallel-group study. Symptoms were assessed for a minimum period of 48 hours before entry. Patients took standard treatment including frequent and small volume feeding, hypo allergic milk, thickening of feeds during 2 weeks. After 2 weeks if any patient had persistence symptoms, included in randomized study. 60 Patients were randomly assigned to the treatment group A (omeprazole 1.2 mg/kg, 5 mg/day for infants 2.5 to 7 kilograms and 10 mg daily for infants to 7-15 kilograms) or group B (syrup of ranitidine with dose 2-4 mg/kg/day in divided 2 doses). Symptoms were assessed during the 2-week treatment period. A parent or guardian completed a symptom diary.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112135330N2**

Registration date: **2012-04-21, 1391/02/02**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-21, 1391/02/02

Registrant information

Name

Mandana Rafeey

Name of organization / entity

Liver and gastrointestinal research center, Tabriz
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Country

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2012-08-21, 1391/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of omeprazole and ranitidine in treatment of symptomatic gastroesophageal reflux disease in infants 2 -12 months old

Public title

Effect of omeprazole on the treatment of gastroesophageal reflux disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infants 2-12 months with body weight over 2.5 kg and full term pregnancy, who had GERD. Exclusion Criteria: Children with previous gastrointestinal surgery, neurologic disease, significant hepatic or renal impairment or a history of significant cardiac or respiratory disease, a history of peptic ulcer disease, proven lactose intolerance, or cow's milk protein intolerance; All children hadn't parental reassurance, use antacids, H2-antagonists, and proton pump inhibitors [PPIs] 4 week before study were excluded.

Age

From **2 years** old to **12 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz university of medical sciences

Street address

Tabriz university of medical sciences

City

Tabriz

Postal code

Approval date

2011-08-21, 1390/05/30

Ethics committee reference number

4314/4/5

Health conditions studied

1

Description of health condition studied

Gastro-oesophageal reflux disease

ICD-10 code

K21.0

ICD-10 code description

Gastro-oesophageal reflux disease with oesophagitis

Primary outcomes

1

Description

weekly GERD symptom score (WGSS)

Timepoint

during 2 weeks

Method of measurement

sum of the 5 selected individual weekly GERD symptom mean frequencies for vomiting/regurgitation (1a), irritability/fussiness (2b), choking/gagging (3a), arching back (4a), and refusal to feed (higher score of 5a and 5b).

Secondary outcomes

1

Description

lack of efficacy per withdrawal criteria, growth parameter

Timepoint

week 4-8

Method of measurement

withdrawal for any reason, time to withdrawal due to lack of efficacy, time to withdrawal for any reason, weekly GERD symptom score (WGSS) ,Physical examinations

Intervention groups

1

Description

omeprazole granules for suspension approximately 1.2mg /kg/ day (5 mg/day for infants 2.5 kg to <7 kg, or 10 mg/day for infants 7kg to 15 kg) for 8 weeks. (Omeprazole is from Chemi daru pharmaceutical company)

Category

Treatment - Drugs

2

Description

syrup of ranitidine by dose 2-4mg/kg/day divided in two doses (ranitidine is from Chemi daru pharmaceutical company).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz children hospital

Full name of responsible person

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz university of medical sciences
Full name of responsible person
Dr. Ali Meshkini
Street address
Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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

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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