Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 (omeprazole1.2 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

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Liver and gastrointestinal research center, Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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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

Name of organization / entity

Tabriz university of medical sciences

Full name of responsible person

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Position

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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