

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparing the effectiveness of omeprazole and ranitidine in the control of signs and symptoms of gastroesophageal reflux disease in preterm neonates unresponsive to conservativel therapy

Protocol summary

2016-09-04, 1395/06/14

Summary

Objectives: The goal of this study is to compare the effectiveness of omeprazole and ranitidine in the treatment of GERD in preterm neonates who do not respond to conservative treatment. **Design:** The study is designed as a double blind randomized controlled trial. **Setting and conduct:** The study will be conducted on 60 otherwise healthy preterm neonates with symptomatic GER attending the neonatology clinic of Shariati Hospital. **Eligible neonates** will be randomly assigned (in blocks of two per site) to a double blind therapeutic trial in two groups receiving either ranitidine or omeprazole. **Outcome** will be assessed by an independent researcher blinded to assignment of neonates. **Major Inclusion and Exclusion criteria:** Study subjects will include healthy and preterm neonates aged 1-28 days with symptoms and signs of GER not responding to conservative therapies including anti-reflux positioning and hypo-allergen regimens. **Intervention:** Neonates who meet the criteria will be randomly assigned to two groups to receive either ranitidine 1 mg/ kg /dose two times per day or omeprazole 0.5 mg/ kg / dose two times per day for one month. **Main outcome variables:** Main outcome is defined as significant improvement in signs and symptoms of GER.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030226876N1**
Registration date: **2016-09-04, 1395/06/14**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effectiveness of omeprazole and ranitidine in the control of signs and symptoms of gastroesophageal reflux disease in preterm neonates unresponsive to conservativel therapy

Public title

Comparing omeprazole and ranitidine in treatment of gastroesophageal reflux disease in pretem neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Healthy preterm infants with troublesome clinical manifestations of gastroesophageal reflux disease (including wheezing, pneumonia, chronic cough, apnea, stridor, failure to thrive, seizure, anemia, sandifer syndrome, irritability, regurgitation, vomiting, rumination); non-responsive to conservative treatment including antireflux positioning and hypo-allergen regimen. Exclusion criteria : Abnormality of GI tract (volvulus, atresia); Drug abuse (morphine, phenobarbital); Mechanical ventilation; Underlying disease (necrotizing enterocolitis, sepsis); Central nervous system abnormalities; Pripheal nervous system abnormalities, Neuro-muscular abnormalities (Myasthenia gravis, Werdnig-Hoffmann disease)

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

4

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

block randomization

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran university Of Medical Sciences, Pursina Street, Ghods Av, Enghelab Square, Tehran, Iran

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Approval date

2016-07-12, 1395/04/22

Ethics committee reference number

IR.TUMS.REC.1395.2766

Health conditions studied

1

Description of health condition studied

Gastroesophageal reflux in premature neonate

ICD-10 code

P78.8

ICD-10 code description

Other specified perinatal digestive system disorders

Primary outcomes

1

Description

GERD symptoms and signs

Timepoint

One week and one month after beginning of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Complications of ranitidine & omeprazole

Timepoint

One week and one month after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention Group 2:Ranitidine1mg/kg/dose/BID

Category

Treatment - Drugs

2

Description

Intervention Group1: Omeprazole 0.5mg/kg/dose /BID

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Negar Sajjadian

Street address

,Shariati Hospital, north of kargar, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Investigator

Full name of responsible person

Dr.Peymaneh Alizadeh Taheri

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Bahrami Hospital, Kiaa Ave, Damavand Ave, Imam Hossein Square, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Investigator

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

Tehran University of Medical Sciences-Shariati Hospita

Full name of responsible person

Negar Sajjadian

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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