

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The comparison of the efficacy of ranitidine with esomeprazole in the recovery rate of signs and symptoms of neonatal gastro esophageal reflux disease

Protocol summary

Study aim

The comparison of the efficacy of esomeprazole with ranitidine in the treatment of GERD in term neonates.

Design

A randomised double blinded clinical trial with two arm parallel group and simple randomization at the individual level and using random number table with allocation concealment by sequentially numbered sealed opaque envelop.

Settings and conduct

The study will be conducted on 60 otherwise healthy term neonates with symptomatic GERD attending to the neonatal clinic of Bahrami Hospital. Eligible neonates will be randomly assigned to a double blind therapeutic trial in two groups receiving either ranitidine or esomeprazole. The physician who cares the patients, the researcher who collects the data and the person who analyses the data are blind.

Participants/Inclusion and exclusion criteria

Major Inclusion Criteria: Study subjects will include healthy and term neonates aged 1-30 days with symptoms and signs of GERD not responding to conservative therapies including anti-reflux positioning, milk thickening and hypo-allergen regimen. Major Exclusion Criteria: 1- Neonates with any underlying diseases, including anomalies or gastrointestinal obstruction, neurological diseases, sepsis, NEC, etc. 2- Using any sedative, relaxant or anticonvulsive medications. 3- History of ventilation therapy.

Intervention groups

Neonates who meet the criteria will be randomly assigned to two groups to receive either ranitidine 2 mg/kg /dose three times per day or esomeprazole 0.5 mg/kg / dose two times per day for one month.

Main outcome variables

En Primary outcome variable includes: The recovery rate in signs and symptoms of GERD. Secondary outcome

variable includes: Complications of ranitidine and esomeprazole in each group.

General information

Reason for update

Acronym

Neonatal GERD

IRCT registration information

IRCT registration number: **IRCT20160827029535N5**

Registration date: **2019-08-21, 1398/05/30**

Registration timing: **prospective**

Last update: **2019-08-21, 1398/05/30**

Update count: **0**

Registration date

2019-08-21, 1398/05/30

Registrant information

Name

Peymaneh Alizadeh Taheri

Name of organization / entity

Tehran University of Medical Sciences, Bahrami Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 7301 3420

Email address

alizadep@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the efficacy of ranitidine with esoprazole in the recovery rate of signs and symptoms of neonatal gastro esophageal reflux disease

Public title

The comparison of the efficacy of two therapeutic regimens in the treatment of gastroesophageal reflux disease in term neonates.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Healthy term neonates aged 1-30days with GERD .

Exclusion criteria:

Healthy term neonates aged 1-30days with GERD not responding to conservative therapies including antireflux positioning, milk thickening, hypoallergic regimens and monotherapy

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

More than 1 sample in each individual

Number of samples in each individual: **1**

Each patient receives the defined drug of his group.

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization at the individual level and using random number table with allocation concealment by sequentially numbered sealed opaque envelop

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, the medical clinician, the researcher who collect data and the who analyze the data are blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

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

City

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Province

Tehran

Postal code

1417653761

Approval date

2019-06-23, 1398/04/02

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.251

Health conditions studied**1****Description of health condition studied**

Gastroesophageal Reflux

ICD-10 code

K21

ICD-10 code description

Gastro-oesophageal reflux disease

Primary outcomes**1****Description**

the comparison of ranitidine with esomeprazole in neonatal GERD

Timepoint

One week and one month after using each drug

Method of measurement

using (I-GERDQ-R) and related scoring

Secondary outcomes**1****Description**

The side effects of each drug

Timepoint

After one week and one month of administering

Method of measurement

Clinical manifestations

Intervention groups

1

Description

Intervention group1: Ranitidine:2mg/kg/dose/TDS

Category

Treatment - Drugs

2

Description

Intervention group 2: Esomeprazole 0.5mg/kg/dose /BID

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami Hospital

Full name of responsible person

Peymaneh Alizadeh Taheri

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Kiaa Ave, Damavand Ave, Imam Hossein Square

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p.alizadet@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bahrami hospital

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bahrami hospital

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

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Peymaneh Alizadeh Taheri

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available