Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of the efficacy of omeprazole with lansoprazole in the recovery rate of neonatal gastro esophageal reflux disease refractory to conservative therapy

Protocol summary

Study aim

The comparison of the efficacy of omeprazole with lansoprazole in the treatment of GERD in term neonates refractory to conservative therapy.

Design

A randomized double blinded clinical trial with two arm parallel groups 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 performed on 120 term neonates with the diagnosis of gastro esophageal reflux disease attending to Bahrami Hospital. Eligible neonates will be randomly assigned to two groups receiving either omeprazole or lansoprazole. The physician and other caregivers, the researcher who collects the data and the person who analyses the data are blind to the study.

Participants/Inclusion and exclusion criteria

Major Inclusion Criteria: Study subjects will include 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 omeprazole with 0 .5 mg/ kg / dose two times per day or lansoprazole 0 .5 mg/ kg / dose two times per day for one month.

Main outcome variables

Primary outcome variable includes: The recovery rate in signs and symptoms of GERD. Secondary outcome variable includes: Complications of omeprazole and lansoprazole in each group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160827029535N10**
Registration date: **2022-02-02, 1400/11/13**
Registration timing: **prospective**

Last update: **2022-02-02, 1400/11/13**
Update count: **0**

Registration date

2022-02-02, 1400/11/13

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

2022-02-20, 1400/12/01

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the efficacy of omeprazole with lansoprazole in the recovery rate of neonatal gastro esophageal reflux disease refractory to conservative therapy

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:

Term neonates aged 1–30 days with gastro esophageal reflux disease

Exclusion criteria:

Neonates with any underlying diseases, including anomalies or gastrointestinal obstruction, neurological disorders, sepsis, NEC, etc. History of using any sedative , relaxant or anticonvulsive medications History of ventilation therapy.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

We used the random number tables from ''Rand Company'' for simple randomization that include random numbers composed of five digits and are printed in blocks of five rows . We chose a starting page in the random number table and dropped a pencil anywhere on the page to indicate a starting block in the table with eyes closed . After starting place was identified, we recorded the first three digits as we used coding system from 001 to108 for number 1 to number 108 of the patients . After that we recorded each three next digits with moving the pencil going down the column to the bottom of the page and then to the top of the next column , and so on till 108 numbers were chosen. We ignored duplicates and omitted the “ three digits “ numbers more than 108. The random numbers for coding numbers from 001 to 054 were considered as group A and the random numbers for coding numbers from 055 to108 considered as group B. According to the sample size of the study , opaque envelopes and cards were provided . Each random number was written on one opaque envelope and each card was put in one opaque envelope according to group A and B. Then the opaque envelopes were sealed and dropped into a box . According to the entrance of each participant, one of the sequentially numbered sealed envelope was opened and the group of intervention was defined.

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

Ghods Av, Enghelab Square

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-11-14, 1400/08/23

Ethics committee reference number

IR.TUMS.CHMC.REC.1400.182

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 omeprazole with lansoprazole 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 administration
Method of measurement
Clinical manifestations

Intervention groups

1

Description
Intervention group: Intervention group1:Omeprazole 0.5mg/kg/dose /BID
Category
Treatment - Drugs

2

Description
Intervention group: Lansoprazole 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
Street address
Kiaa Ave, Damavand Ave, Imam Hossein Square
City
Tehran
Province
Tehran
Postal code
1641744991
Phone
+98 21 7301 3413
Fax
+98 21 7756 8809
Email
p.alizadet@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Akbar Fotoohi
Street address
Central Staff of Tehran University of Medical Sciences, No:226,-Keshavarz Boulvard
City
Tehran
Province
Tehran
Postal code
1417614411
Phone
+98 21 6111 2992
Email
afotouhi@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
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
Street address
Shahid Kiaii Street,Damavand Avenue, Imam Hossein Square
City
Tehran
Province
Tehran
Postal code

1641744991
Phone
+98 73013413
Fax
+98 21 7756 8809
Email
p.alizadet@yahoo.com

Person responsible for scientific 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
Street address
Shahid Kiaa Street, Damavand Avenue, Imam Hossein Square
City
Tehran
Province
Tehran
Postal code
1641744991
Phone
+98 21 7301 3413
Fax
+98 21 7756 8809
Email
p.alizadet@yahoo.com

Person responsible for updating data

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
Street address
Shahid Kiaii Street, Damavand Avenue, Imam Hossein
City
Tehran
Province
Tehran
Postal code
1641744991
Phone
+98 21 7301 3413
Email
p.alizadet@yahoo.com

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