

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The comparison of the efficacy of two different doses of lansoprazole in the treatment of neonatal gastro esophageal reflux disease refractory to conservative therapy

Protocol summary

Study aim

The comparison of the efficacy of two different doses of lansoprazole in the treatment of GERD in term neonates refractory to conservative therapy.

Design

A randomized 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 120 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 of 60 patients receiving two different doses of lansoprazole. The participants, the medical clinician, the researcher who collect data and the statist who analyzes the data, are blind .

Participants/Inclusion and exclusion criteria

Major Inclusion Criteria: Healthy term neonates aged 1-30days with GERD not responding to conservative therapy (including anti-reflux positioning, milk thickening and feeding with lower volume of milk and shorter interval).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 lansoprazole with 0 .5 mg/ kg / dose two times per day or lansoprazole 0 .75 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 lansoprazole in each group.

General information

Reason for update

Acronym

Neonatal GERD

IRCT registration information

IRCT registration number: **IRCT20160827029535N9**

Registration date: **2022-01-03, 1400/10/13**

Registration timing: **prospective**

Last update: **2022-01-03, 1400/10/13**

Update count: **0**

Registration date

2022-01-03, 1400/10/13

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

2022-12-22, 1401/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The comparison of the efficacy of two different doses of lansoprazole in the treatment of neonatal gastroesophageal reflux disease refractory to conservative therapy

Public title
The comparison of the efficacy of two different doses of lansoprazole 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 not responding to conservative therapy (including anti-reflux positioning, milk thickening and feeding with lower volume of milk and shorter interval).
Exclusion criteria:
1-Neonates with any underlying diseases, including anomalies or gastrointestinal obstruction, neurological disorders, sepsis, NEC, etc.2-Using any sedative , relaxant or anticonvulsive medications .3-History of ventilation therapy.

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

Gender
Both

Phase
2-3

Groups that have been masked

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

Sample size
Target sample size: **120**
More than 1 sample in each individual
Number of samples in each individual: **60**
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 statist who analyzes the data

are blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
کمیته اخلاق دانشگاه علوم پزشکی تهران
Street address
میدان انقلاب-خیابان قدس-خیابان پورسینا- دانشگاه علوم پزشکی
City
Tehran
Province
Tehran
Postal code
1417653761

Approval date
2021-11-03, 1400/08/12

Ethics committee reference number
IR.TUMS.CHMC.REC.1400.173

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 two different doses of lansoprazole in treatment of refractory neonatal GERD to conservative therapy

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 dose of lansoprazole

Timepoint

After one week and one month of administration

Method of measurement

Clinical manifestations

Intervention groups**1****Description**

Intervention group1: Intervention group1:Lansoprazole
0.5/kg/dose /BID

Category

Treatment - Drugs

2**Description**

Intervention group2: Lansoprazole 0.75mg/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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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

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

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

Tehran University of Medical Sciences

Position

Full Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

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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