Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

The comparison of the efficacy of ranitidine plus metoclopramide with lansoprazole plus metoclopramide in the recovery rate of signs and symptoms of neonatal gastro esophageal reflux disease unresponsive to conservative and monotherapy.

Protocol summary

Study aim

The comparison of the efficacy of lansoprazole plus metoclopramide with ranitidine plus metoclopramide in the treatment of GERD in term neonates who do not respond to conservative and monotherapy.

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 plus metoclopramide or lansoprazole plus metoclopramide. 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 lansoprazole 0 .7 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 ranitidine , lansoprazole and metoclopramide in each group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160827029535N3**
Registration date: **2018-01-30, 1396/11/10**
Registration timing: **prospective**

Last update: **2018-01-30, 1396/11/10**
Update count: **0**

Registration date

2018-01-30, 1396/11/10

Registrant information

Name

Peymaneh Alizadeh Taheri

Name of organization / entity

Tehran University of Medical Sciences, Bahrami Hospital

Country

Iran (Islamic Republic of)

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+98 21 7301 3420

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date
2018-03-21, 1397/01/01
Expected recruitment end date
2019-03-21, 1398/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of the efficacy of ranitidine plus metoclopramide with lansoprazole plus metoclopramide in the recovery rate of signs and symptoms of neonatal gastro esophageal reflux disease unresponsive to conservative and monotherapy.

Public title
The comparison of the efficacy of two combined 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 not responding to conservative therapies including antireflux positioning, milk thickening, hypoallergic regimens and monotherapy.
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
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
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 physicians who care the participants; the researcher who collects the data and the person who analyses the data are blind to the study.
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 Avenue, Enghelab Square Tehran Tehran Iran, Islamic Republic Of Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2017-10-15, 1396/07/23
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1396.3714

Health conditions studied

1

Description of health condition studied
Gastroesophageal reflux in mature neonate
ICD-10 code
P78.8
ICD-10 code description
Other specified perinatal digestive system disorders

Primary outcomes

1

Description
The response rate of GERD symptoms and signs in each intervention group
Timepoint
One week and one month after beginning of intervention
Method of measurement
Questionnaire

Secondary outcomes

1

Description
The rate of complications of ranitidine , lanzoprasole and omeprazole in each group of intervention
Timepoint
One week and one month after beginning of intervention
Method of measurement
Questionnaire

Intervention groups

1

Description
In group 1 intervention: Ranitidine 2 mg/kg TDS plus metoclopramide 0/15 mg/kg TDS for one month
Category
Treatment - Drugs

2

Description
In group 2 intervention: lansoprazole 0/7 mg/kg/BID plus metoclopramide 0/15 mg/kg TDS for one month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bahrami hospital
Full name of responsible person
Peymaneh Alizadeh Taheri
Street address
Bahrami Hospital, Shahid Kiaii Street, Damavand Avenue, Imam Hossein Square
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p.alizadet@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
Full name of responsible person
Dr. Peymaneh Alizadeh Taheri
Street address
Bahrami Hospital, Shahid Kiaii Street, Damavand Avenue, Imam Hossein Square
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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
Investigator
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences, Bahrami Hospital
Full name of responsible person
Dr. 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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Position
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Web page address

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