Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of erythromycin and metoclopramide in the treatment of dysmotility in premature neonates

Protocol summary

Study aim

Determining the effect of erythromycin and metoclopramide in improving gastrointestinal symptoms in infants with dysmotility Determining the time required for total parenteral nutrition in premature infants treated with erythromycin and metoclopramide Comparison of side effects of erythromycin and metoclopramide on premature infants Comparison of hospitalization duration of infants treated with erythromycin and metoclopramide Comparison of the duration of receiving antibiotics in infants treated with erythromycin and metoclopramide

Design

A comparative clinical trial, parallel groups, no blinding, randomized with non-equivalent blocks with pilot method, phase 3 on 60 patients, randomization will be done with the website sealedenvelope.com

Settings and conduct

Premature babies hospitalized in the Kamali Hospital NICU included in criteria are examined by the responsible researcher and their clinical evaluation is performed by another researcher who is not aware of the randomized list

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Infant with gestational age of under 32 weeks and postnatal age of more than 2 weeks 2. Signs of dysmotility; vomiting, no defecation for more than three days, abdominal distention 3. Absence of gastrointestinal anomaly; Necrotizing enterocolitis(NEC), malrotation, intestinal atresia Exclusion criteria: 1. Drug sensitivity 2. Parental dissatisfaction with participation in the study 3. Aggravation of dysmotility symptoms 4.The impossibility of assessing outcome due to transfer to another center or loss of the infant 5. Positive CRP or symptoms of gastrointestinal anomalies; NEC, malrotation, intestinal atresia

Intervention groups

Infants are divided into two groups. one group is treated with erythromycin and other with metoclopramide.

Main outcome variables

Feces volume; Daily vomiting frequency; Enteral nutrition intake volume; Lavage frequency

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220524054983N1**
Registration date: **2024-01-10, 1402/10/20**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-10, 1402/10/20**
Update count: **0**

Registration date

2024-01-10, 1402/10/20

Registrant information

Name

zahra arabiaan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3252 3121

Email address

zahraarabiaan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-09, 1402/10/19

Expected recruitment end date

2024-04-07, 1403/01/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of erythromycin and metoclopramide in the treatment of dysmotility in premature neonates

Public title
Comparison of erythromycin and metoclopramide on gastrointestinal disorders in premature infants

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Neonates with gestational age of more than 32 weeks and postnatal ago of more than 2 weeks Signs and symptoms of dysmotility; vomiting, abdominal distention, failure to defecate for more than 3 days Absence of gastrointestinal anomaly; malrotation, intestinal atresia, necrotizing enterocolitis Neonates with minimum weight of 800 grams and maximum of 1500 grams

Exclusion criteria:
Drug reactions Worsening of dysmotility signs and symptoms Positive CRP in laboratory tests or any suspicion about gastrointestinal anomalies including intestinal malrotation, necrotizing enterocolitis and intestinal atresia The impossibility of assessing the outcome due to transfer to another center or the loss of the infant. Dissatisfaction with participation in the study

Age
From **8 months** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Premature neonates hospitalized in the NICU are examined based on the entry and exit criteria, and with the individual block randomization method, we separate the neonates by statistical software and the neonates will be evaluated by the responsible researcher. Also, the size of the blocks will be unmatched to hide the allocation.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Alborz University of Medical Sciences

Street address
No. 34.1, 6th Boostan Ave., North Neda Blvd., Mehran Sq., Azimieh

City
karaj

Province
Alborz

Postal code
3155716911

Approval date
2023-11-18, 1402/08/27

Ethics committee reference number
IR.ABZUMS.REC.1402.219

Health conditions studied

1

Description of health condition studied
Gastrointestinal dysmotility

ICD-10 code
P92.9

ICD-10 code description
Feeding problem of newborn, unspecified

Primary outcomes

1

Description
The improvement in clinical symptoms of dysmotility in premature neonate after a course of treatment.

Timepoint
Measuring the frequency of daily feeding and lavage until the end of the treatment period

Method of measurement
Daily enteral feeding volume

Secondary outcomes

1

Description
Time of administration of the drugs under study

Timepoint
At the beginning of the study and then daily

Method of measurement
Insertion in data query form including date and hour

2

Description
Lavage frequency

Timepoint
Each lavage
Method of measurement
Nasogastric tube

3

Description
Duration of intravenous feeding
Timepoint
Initiation and termination of Intravenous nutrition
Method of measurement
Patient information file

4

Description
Enteral nutrition initiation time
Timepoint
At the beginning of the study
Method of measurement
Patient information file

5

Description
Enteral nutrition intake
Timepoint
At the beginning of the study and then daily
Method of measurement
Patient information file

6

Description
Vomiting frequency
Timepoint
Each time vomiting
Method of measurement
Patient information file

7

Description
Frequency of defecation
Timepoint
Daily
Method of measurement
Frequency of diaper change

8

Description
Gender
Timepoint
At the beginning of the study
Method of measurement
Patient information file

9

Description
Time of admission
Timepoint
At the beginning of the study
Method of measurement
Patient information file

Intervention groups

1

Description
Intervention group: metoclopramide drops, made in Iran, Abidi company, one drop every 8 hours, oral
Category
Treatment - Drugs

2

Description
Intervention group: erythromycin syrup, made in Iran, Loghman company, 10 mg per kilogram of weight, every 6 hours, oral
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali hospital
Full name of responsible person
Zahra Arabiaan
Street address
Kamali hospital, Kamali Ave., Shohada' Sq., Shahid Beheshti Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj 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
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Kamran Behrouzi
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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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