Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing outcome of oral administration of erythromycin and metoclopramide of feeding intolerance in preterm newborn with Gestational age <32 week in Semnan Amiralmomenin Hospital

Protocol summary

Study aim
Comparing outcome of oral administration of erythromycin and metoclopramide of feeding intolerance in preterm newborn with Gestational age <32 week in Semnan Amiralmomenin Hospital

Design
Clinical trials without a control group, community-based and pragmatic, with parallel groups, randomized (randomized block design), without control with placebo, single center trial.

Settings and conduct
Amiralmomenin Hospital, Semnan

Participants/Inclusion and exclusion criteria
Inclusion criteria: Preterm infants less than or equal to 32 weeks. Exclusion criteria: Congenital heart disease; Gastrointestinal anomalies; Hypoxic injuries.

Intervention groups
Intervention group 1: Based on NICU feeding protocol; erythromycin 10 mg/kg every 6 hours for 2 days and then 4 mg/kg every 6 hours. Intervention group 2: Based on the NICU feeding protocol; metoclopramide at a dose of 0.1 mg/kg every 8 hours.

Main outcome variables
Food Intolerance

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151228025732N37**
Registration date: **2019-03-23, 1398/01/03**
Registration timing: **retrospective**

Last update: **2019-03-23, 1398/01/03**
Update count: **0**

Registration date
2019-03-23, 1398/01/03

Registrant information

Name
Alireza Emadi

Name of organization / entity
Semnan University of Medical Sciences, Semnan, Iran

Country
Iran (Islamic Republic of)

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+98 23 3345 1336

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are20935@semums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-17, 1397/04/26

Expected recruitment end date
2019-03-16, 1397/12/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing outcome of oral administration of erythromycin and metoclopramide of feeding intolerance in preterm newborn with Gestational age <32 week in Semnan Amiralmomenin Hospital

Public title
Comparing outcome of oral administration of erythromycin and metoclopramide of feeding intolerance in preterm newborn with Gestational age <32 week in Semnan Amiralmomenin Hospital

Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Preterm infants less than or equal to 32 weeks
Exclusion criteria:
Congenital heart disease Gastrointestinal anomalies Hypoxic injuries
Age
No age limit
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization; Individual; Random Number Tables. Randomized permutation blocks (block 2). Using Excel software to generate random number tables.
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 Semnan University of Medical Sciences
Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2018-07-17, 1397/04/26
Ethics committee reference number
IR.SEMUMS.REC.1397.118

Health conditions studied

1

Description of health condition studied
Food Intolerance
ICD-10 code
K90.4
ICD-10 code description
Malabsorption due to intolerance, not elsewhere classified

Primary outcomes

1

Description
Baby weight
Timepoint
Before and after intervention
Method of measurement
Balance

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Based on NICU feeding protocol; erythromycin 10 mg/kg every 6 hours for 2 days and then 4 mg/kg every 6 hours.
Category
Treatment - Drugs

2

Description
Intervention group 2: Based on the NICU feeding protocol; metoclopramide at a dose of 0.1 mg/kg every 8 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Al-Momenin Hospital
Full name of responsible person
Shamsollah Noripour
Street address
Amir Al-Momenin Hospital, Mostafa Khomeini Blvd
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3514799442

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Fatemeh Ehsani
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fatemehehsani59@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Semnan 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
Semnan University of Medical Sciences
Full name of responsible person
Shamsollah Noripour
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for updating data

Contact
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Semnan University of Medical Sciences
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Alireza Moghimi
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Expert physician
Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
-

When the data will become available and for how long
-

To whom data/document is available
Only available to scholars working in academic institutions.

Under which criteria data/document could be used
In case of relevant studies.

From where data/document is obtainable
Shamsollah Noripour. Amir Al-Momenin Hospital, Mostafa Khomeini Blvd. 00989125198522

What processes are involved for a request to access data/document
-

Comments