

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

2019-03-23, 1398/01/03

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

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

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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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
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Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
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

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Comments