Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Randomize clinical trial on determining the effect of Erythromycin on the establishment of feeding in infants under 32 weeks gestation

Protocol summary

Summary

Objectives:To determine the effect of erythromycin on the establishment of feeding in infants under 32 weeks gestation. Design:randomized, double-blind, clinical trial; Study population: 40 preterm infants under 32 weeks gestation hospitalized in the neonatal intensive care unit with a diagnosis of dietary intolerance randomly divided into two groups; Study type: one center; Study phase: Phase II. Setting and conduct: The first group (n=20) that Erythromycin ethyl succinate oral (10 mg per kg every six hours to two days, followed by 4 mg per kg every six hours to 5 days) and group II (n=20) treated with normal saline will receive the same dose and instructions. The duration of treatment for both groups will be equivalent to one week. Participants: Inclusion criteria : Infants less than 32 weeks gestational age or weighting less than 1800 g and the minimum age is 5 days after birth and are clinically stable economical state (normal blood pressure Episodes of bradycardia and hypoxemia not) feeding intolerance for less than 75 milli liters per kilogram per day 14 days remain gay or gastric material by more than 50% of 3 hours, which occurred at least two times during the 24 hour period or more than 30% of gastric residues 3 hours ago happened at least three times. Exclusion criteria : lethal congenital malformations congenital or chromosomal disorders, cyanotic heart disease, diseases of the gastrointestinal tract obstruction (mal rotation, atresia and Omphalocele, etc.), gastrointestinal surgeries in 14 days ago, NEC suspected or confirmed in the last 7 days, definite or clinical sepsis, metabolic disorders or electrolytic , and treatment with any of the following medications at the onset of feeding intolerance fentanyl , indomethacin , pancuronioum. Interventions : The use of erythromycin ethylene succinate in the study group. Main outcome: Infant can tolerate 150 milliliter per kilogram in at least 24 hours in one day; side effects of treatment include diarrhea, vomiting, pyloric stenosis and evidence of necrotizing enterocolitis; the length of stay in ICU and hospital.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121925591N1**
Registration date: **2016-06-12, 1395/03/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-06-12, 1395/03/23

Registrant information

Name
Maryam Saboute
Name of organization / entity
Akbar abadi Hospital
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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences Research Center

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Randomize clinical trial on determining the effect of Erythromycin on the establishment of feeding in infants under 32 weeks gestation

Public title
Influence of Erythromycin ethyl succinate oral on establishment of feeding in preterm infants

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Infants less than 32 weeks gestational age or weighting less than 1800 g with minimum age of 5 days and clinically stable (Normal blood pressure, not having episodes of bradycardia and hypoxemia); Feeding intolerance for less than 75 milliliters per kilogram per day in 14 days; material remaining in the stomach for more than 50% in 3 hours before, which occurred at least two times during the 24 hours; Vomiting more than 30% of gastric residues in 3 hours that happened at least three times Exclusion criteria: Lethal congenital malformations congenital or chromosomal disorders; Cyanotic heart disease; Diseases of the gastrointestinal tract obstruction (Mal rotation, Atresia and Omphalocele, etc.); Gastrointestinal surgeries in 14 days ago; NEC suspected or confirmed in the last 7 days; Definite or clinical sepsis; Metabolic disorders or electrolytic; Treatment with any of the following medications at the onset of feeding intolerance (Fentanyl , Indomethacin, Pancuronioum)

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences, School Medicine

Street address
Iran University of Medical Sciences , Hemmat high way , Tehran , Iran

City
Tehran

Postal code

Approval date
2015-11-09, 1394/08/18

Ethics committee reference number
IR.IUMS.REC.1394-22688

Health conditions studied

1

Description of health condition studied
Premature infants

ICD-10 code
P78.9

ICD-10 code description
Perinatal digestive system disorder, unspecified

Primary outcomes

1

Description
Feeding tolerance of preterm infants

Timepoint
5 days after birth less than 32 weeks, less than 1800 gr

Method of measurement
Weight

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Erythromycin Ethyl Succinate oral (10 mg per kg every six hours to two days, followed by 4 mg per kg every six hours to 5 days)

Category
Treatment - Drugs

2

Description
Control group: Normal saline (placebo) (10 mg per kg every six hours to two days, followed by 4 mg per kg every six hours to 5 days)

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Asghar Children Hospital,

Full name of responsible person
Dr.Maryam Saboute

Street address
Ali Asghar Children Hospital, Vahid Dastgerdi St., Shariati Ave

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences Research Center

Full name of responsible person
Dr. Seyed Ali Javad Mousavi

Street address
3rd floor, Setad building, in front of Milad Hospital, Hemat

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences Research Center

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Ali Asghar Children Hospital

Full name of responsible person
Maryam Saboute

Position
Assistant professor, Neonatologist

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty