

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 , pancuronium. **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

Country

Iran (Islamic Republic of)

Phone

+98 21 5563 2277

Email address

saboute.m@iums.ac.ir

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, Pancuronium)

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

Street address

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

City

Tehran

Postal code

Phone

+98 21 5563 2277

Fax

Email

saboutem@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ali Asghar Children Hospital

Full name of responsible person

Maryam Saboute

Position

Assistant Professor

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

Phone

+98 21 5563 2277

Fax

Email

saboutem@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ali Asghar Children Hospital

Full name of responsible person

Dr.Maryam Saboute

Position

Assistant Professor, Neonatologist

Other areas of specialty/work

Street address

Ali Asghar Children Hospital, Vahid Dastgerdi St.,
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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