Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of intermediate dose of oral Erythromycin on feeding intolerance in premature infants

Protocol summary

Study aim

Determining the effect of intermediate dose of oral Erythromycin on treating feeding intolerance in preterm neonates

Design

In this research 84 preterm neonates with inclusion criteria admitted in Alzahra and Beheshti hospitals are selected. Neonates were randomly divided in to two groups based on numbering syringes of Erythromycin and placebo. neonates are receiving 20 cc/kg/ day feeding and if they tolerate it, 20 cc/kg/day feeding is added every day to receive to 150 cc/ kg/ day. neonates are randomly divided in to two groups. The first group is receiving 20 mg/kg/day erythromycin for 8 days every 6 hours and control group is receiving distilled water, respectively. The principal investigator, blinded to the syringes' content, was responsible for patient selection and allocated the infants to the interventions in sequence of being entered into the study and based on the table of random numbers

Settings and conduct

Alzahra and Shahid beheshti hospitals

Participants/Inclusion and exclusion criteria

Preterm infants weighing less than 1800 g who have had frequent milk intolerance without any signs of infection or serious anomalies

Intervention groups

neonates are receiving 20 cc/kg/ day feeding and if they tolerate it, 20 cc/kg/day feeding is added every day to receive to 150 cc/ kg/ day. neonates are randomly divided in to two groups. The first group is receiving 20 mg/kg/day erythromycin for 8 days every 6 hours and control group is receiving distilled water, respectively

Main outcome variables

time duration to receive to 75. 110, 150 cc/kg/ day feeding volume

General information

Reason for update

Acronym

erythromycin

IRCT registration information

IRCT registration number: **IRCT20120614010026N10**
Registration date: **2018-01-14, 1396/10/24**
Registration timing: **retrospective**

Last update: **2018-01-14, 1396/10/24**
Update count: **1**

Registration date

2018-01-14, 1396/10/24

Registrant information

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Amir mohammad Armanian
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Isfahan university of medical science

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

2016-03-20, 1395/01/01

Actual recruitment end date

2017-09-21, 1396/06/30

Trial completion date

empty

Scientific title
Evaluating the effect of intermediate dose of oral Erythromycin on feeding intolerance in premature infants

Public title
The effect of Erythromycin on feeding intolerance in premature infants
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
premature infants weight lower than 1800 grams feeding volume less than 75 cc/kg/ day in the 14th day after birth frequent lavage (i.e. => 2 times lavage; >50% of milk volume) parents willingness
Exclusion criteria:
presence of sepsis gastrointestinal anomalies cyanotic heart disease history of operation on gastrointestinal system in the first 14 days after birth consumption of medication effective in erythromycin metabolism in the same time incidence of arrhythmia or prolonged QT interval parents unwillingness
Age
From **14 days** old to **1 month** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **84**
Actual sample size reached: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
Table of random numbers
Blinding (investigator's opinion)
Double blinded
Blinding description
The syringes of Erythromycin and distilled water are similar in appearance, color and cover. A trained nurse who is not participated in this study, numbered syringes and give them to this study colleague. The colleague divided these syringes among neonates without knowing a bout content of syringe
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan university of medical science
Street address
isfahan, hezar jarib street, isfahan university of medical sciene
City
isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2016-09-22, 1395/07/01
Ethics committee reference number
IR.MUI.REC.1395.3.994

Health conditions studied

1

Description of health condition studied
feeding intolerance
ICD-10 code
p92.3
ICD-10 code description
Underfeeding of newborn

Primary outcomes

1

Description
time duration to reach to 75, 110 and 150 cc/kg/ day feeding volume
Timepoint
daily, during intervention
Method of measurement
observation

Secondary outcomes

1

Description
time duration of oxygen dependency
Timepoint
during intervention
Method of measurement
observation

2

Description
time duration of hospitalization
Timepoint

during intervention
Method of measurement
observation

3

Description
sepsis incidence
Timepoint
during intervention
Method of measurement
physical examination

4

Description
necrotizing enterocolitis incidence
Timepoint
during intervention
Method of measurement
physical examination

Intervention groups

1

Description
in intervention group: erythromycin syrup, 20 mg/kg/day, every 6 hours. for 8 days in control group: distilled water, 20 cc/kg/day, every 6 hours, for 8 days
Category
Treatment - Drugs

2

Description
Control group: distilled water equal volume of erythromycin for 8 days
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Hospital
Full name of responsible person
Dr Amir-mohammad Armanian
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Beheshti Hospital, In front of Aseman Holtel, Motahari Street, Isfahan City, Iran country
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2

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Dr Amir-mohammad Armanian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mehdi Nematbakhsh
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Isfahan University of Medical Science, Hezar Jarib Street, Isfahan City, Iran Country
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Amir-mohammad Armanian
Position
Neonatalogist/ Associate 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)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
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
Not applicable