

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 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

##### Name

Amir mohammad Armanian

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1235 5059

##### Email address

armanian@med.mui.ac.ir

##### 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

Isfahan

##### 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  
**Street address**  
Beheshti Hospital, In front of Aseman Holtel, Motahari Street, Isfahan City, Iran country  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8174673461  
**Phone**  
+98 31 3236 7001  
**Email**

armanian@med.mui.ac.ir

### 2

**Recruitment center**  
**Name of recruitment center**  
Alzahra hospital  
**Full name of responsible person**  
Dr Amir-mohammad Armanian  
**Street address**  
Alzahra Hospital, Shohadaye Sofe Streets, Isfahan City, Iran Country  
**City**  
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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  
**Street address**  
Isfahan University of Medical Science, Hezar Jarib Street, Isfahan City, Iran Country  
**City**  
Isfahan  
**Province**  
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**Postal code**  
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+98 31 3668 0048  
**Email**  
armanian@med.mui.ac.ir  
**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

**Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Amir-mohammad Armanian

**Position**

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**Latest degree**

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**Web page address**

## Person responsible for scientific 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**

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**Province**

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**Postal code**

8174673461

**Phone**

## 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