

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Survey the effect of oral erythromycin(low dose) on feeding tolerance in admitted premature neonates at imam Reza hospital NICU

Protocol summary

Summary

The purpose of this study was to evaluate the effectiveness of oral erythromycin(low dose) on feeding tolerance in admitted premature neonates at kermanshah-imam Reza hospital NICU. The inclusion criteria were : preterm babies with gestational age between 28-34 w and birth weight between 1000-1800gr 2)postnatal age less than 3 days of life Exclusion criteria were: 1) birth asphexia 2) electrolyte imbalance 3) the presence of major congenital abnormalities; 4) necrotizing enterocolitis 5) formula feeding 6) cyanotic congenital heart disease 7) usage of prokinetic agents (such as metoclopramide) 8) mechanical ventilation 9) history of surgery . preterm newborns with postnatal age less than 3 days were included. The sample size included 70 preterm neonates. newborns were randomized (using parallel blocks of 10 according to a predetermined list of random number) to receive one of the following 2 groups: case group(n=35) received oral erythromycin(2.5 mg/kg/q6h for ten 10 days) and control group(no intervention)(n=35) .The neonate in both groups received breast milk. And feeding started within the first three days of life. The primary outcome measure was the duration required by the infant to achieve full enteral feeds(150ml/kg/day for at least 24h .The Secondary outcome measures were duration of hospital admission and vomiting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110104961N5**

Registration date: **2012-09-15, 1391/06/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-09-15, 1391/06/25

Registrant information

Name

Homa Babaei

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00988314276303 2292 داخلی

Email address

homa_babaei@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2011-08-06, 1390/05/15

Expected recruitment end date

2012-08-05, 1391/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey the effect of oral erythromycin(low dose) on feeding tolerance in admitted premature neonates at imam Reza hospital NICU

Public title

Survey the effect of oral erythromycin(low dose) on feeding tolerance in admitted premature neonates at imam Reza hospital NICU

Purpose

Prevention

Inclusion/Exclusion criteria

The inclusion criteria were : preterm babies with gestational age between 28-34 w and birth weight between 1000-1800gr 2) postnatal age less than 3 days of life Exclusion criteria were: 1) birth asphexia 2) electrolyte imbalance 3) the presence of major congenital abnormalities; 4) necrotizing enterocolitis 5) formula feeding 6) cyanotic congenital heart disease 7) usage of prokinetic agents (such as metoclopramide) 8) mechanical ventilation 9) history of surgery

Age

To 3 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

clinical research developmental center, Kermanshah university of medical sciences, Kermanshah, Iran

City

kermanshah

Postal code

6714415333

Approval date

2011-07-24, 1390/05/02

Ethics committee reference number

7872/پ/707/7/آ

Health conditions studied

1

Description of health condition studied

feeding tolerance

ICD-10 code

p92

ICD-10 code description

Feeding problems of newborn

Primary outcomes

1

Description

feeding tolerance

Timepoint

q3h

Method of measurement

inspection

Secondary outcomes

1

Description

duration of admission

Timepoint

daily

Method of measurement

medical record

Intervention groups

1

Description

The intervention group received oral erythromycin (2.5 mg/kg/q6h) plus breast milk

Category

Treatment - Drugs

2

Description

control group (no intervention) only received breast milk

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital, Kermanshah University of Medical Sciences

Full name of responsible person

Street address

City

kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr farid Najafi

Street address

Deputy of Research, Kermanshah University of Medical Sciences

City

kermnshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences

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**

Kermanshah University of Medical Sciences

Full name of responsible person

Homa Babaei, MD

Position

neonatologist

Other areas of specialty/work**Street address**

Department of Pediatrics, Kermanshah University of Medical Sciences

City

kermanshah

Postal code**Phone**

+98 83 1427 6303

Fax**Email**

homa_babei@kums.ac.ir homa_babaei@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

homa babaei

Position

neontologist

Other areas of specialty/work**Street address**

Department of pediatrics ,Kermanshah University of Medical Sciences

City

kermnshah

Postal code

6714415333

Phone

+98 83 1427 6303

Fax**Email**

homa_babaei@kums.ac.ir homa_babaei@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

homa babaei

Position

neoaatologist

Other areas of specialty/work**Street address**

Department of Pediatrics, Kermanshah University of Medical Sciences

City

kermanshah

Postal code

6714415333

Phone

+98 83 1427 6303

Fax**Email**

homa_bbaei@kums.ac.ir homa_babei@yahoo.com

Web page address

www.kums.ac.ir

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