

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of metoclopramide therapy compared with placebo in improving oral feeding intolerance in preterm infants

Protocol summary

Summary

Advancing feedings to full enteral feeding is highly difficult and it may last about 2-3 weeks. This study designed to evaluate the efficacy of metoclopramide in the treatment of feeding intolerance in preterm neonates. 120 preterm infants less than 36 weeks with feeding intolerance and without anomaly include and term neonate and neonate with anomaly exclude and were allocated into two groups: treatment group were received intravenous metoclopramide (0.4mg/kg /day divided 3 times daily,) and control group were received placebo (Sterile water for injection). Full enteral feeding (150 ml/kg/day) after the start of treatment and mean feeding start time, mean time of feeding completion, mean number of vomiting and lavage and mean number of feeding cessations will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305188680N3**

Registration date: **2014-01-12, 1392/10/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-01-12, 1392/10/22

Registrant information

Name

Mirhadi Mussavi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3327 2094

Email address

mousavi-m@medilam.ac.ir

Recruitment status

Recruitment complete

Funding source

Ilam University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of metoclopramide therapy compared with placebo in improving oral feeding intolerance in preterm infants

Public title

Metoclopramide effect in improving feeding tolerance in neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Preterm neonate less than 36 weeks with feeding intolerance ; neonate without anomaly;
Exclusion criteria : neonate with congenital anomalies

Age

From **3 years** old to **28 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

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**

Ilam University of Medical Science

Street address

Ilam.Banganjab

City

Ilam

Postal code**Approval date**

2012-05-30, 1391/03/10

Ethics committee reference number

EC/92/H/158

Health conditions studied**1****Description of health condition studied**

enteral feeding intolerance

ICD-10 code

p78.9

ICD-10 code description

Perinatal digestive system disorder, unspecified

Primary outcomes**1****Description**

enteral feeding intolerance

Timepoint

Q3h

Method of measurement

no vomitting,no gastric residua

Secondary outcomes**1****Description**

complet full enteral feeding

Timepoint

daily

Method of measurement

volum of feeding per day

Intervention groups**1****Description**

Metoclopramide. /13 mg/kg Q 8h intavenously

Category

Treatment - Drugs

2**Description**

sterile water for injection . /13 CC q 88 intravenously

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

NICU Ward , Mostafa Khomeini Hospital , Ilam , Iran

Full name of responsible person

Dr.Mirhadi,Mussavi

Street address

Keshvary sq

City

Ilam

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ilam University of Medical Sciences

Full name of responsible person

Dr.Morovat Taheri Kalani

Street address

Banganjab

City

Ilam

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

Yes

Title of funding source

Ilam 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

Ilam
Postal code
Phone
+98 84 1222 7126
Fax
Email
Drmussaviahadi@yahoo.com
Web page address

Person responsible for general inquiries

Contact

Name of organization / entity
Ilam University Of Medical Sciences
Full name of responsible person
Mirhadi Mussavi
Position
Assisstant proffesor
Other areas of specialty/work
Street address
Banganjab
City
Ilam
Postal code
Phone
+98 41 1327 2094
Fax
Email
Drmussaviahadi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ilam University of medical sciences
Full name of responsible person
Mirhadi Mussavi
Position
Neonatologist
Other areas of specialty/work
Street address
Banganjab
City

Person responsible for updating data

Contact

Name of organization / entity
Ilam University Of Medical Sciences
Full name of responsible person
Mirhadi Mussavi
Position
Neonatologist
Other areas of specialty/work
Street address
Ilam
City
Ilam
Postal code
Phone
00
Fax
Email
Web page address

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