Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of metoclopramide administration to mother on newborn’s bilirubin and mother’s prolactine: a randomized controlled clinical trial

Protocol summary

Summary

Objectives: To determine the effect of metoclopramide administration to mother on newborn’s bilirubin and mother’s prolactin. Design: A randomized controlled trial with two parallel arms. Conduct: This study will be conducted on 112 mothers who hospitalized in the postpartum wards of Taleghani and Alzahra hospitals. Eligible women who have willingness to participate in the study will be assigned into two groups of intervention (receiving metoclopramide) and control (receiving placebo) through stratified block randomization (based on the type of delivery) with a block sizes of four and six, and the allocation ratio of 1: 1. Participants: Hospitalized women in the postpartum wards of Taleghani and Alzahra hospitals. Interventions: metoclopramide and placebo tablets, both with dosages of 10 mg three times daily after breakfast, lunch and dinner will be consumed by participants. The intervention will be from 2 to 10 hours after birth and will be continued until the fifth day. The main outcome variables include the neonatal total bilirubin that will be assessed by Bilicheck (TCB) on the first and sixth day of study. Also, serum level of prolactin will be assessed in the next day after starting of the intervention and sixth day. Secondary outcome variables include volume of milk will be assessed two hours after the last breastfeeding in the first and sixth day. As well as satisfaction checklist of breastfeeding status will be completed by questioning of mothers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101710324N34**
Registration date: **2017-02-20, 1395/12/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-20, 1395/12/02

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of metoclopramide administration to mother on newborn’s bilirubin and mother’s prolactine: a randomized controlled clinical trial

Public title

The effect of metoclopramide administration to mother on newborn’s bilirubin and mother’s prolactine

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Healthy full-term pregnancy; Mothers with singleton pregnancy; Being Lactating, and having tendency and motivation to breast-feeding; Living in Tabriz; Willingness to continue in the study; -Having at least literacy of reading and writing. Exclusion criteria: Newborns with birth defects; Newborns that need to neonatal intensive cares; Neonatal jaundice in first day after birth; Neonatal metabolic disease; Taking of hormonal drugs by mothers such as estrogen; Taking of medications that affect the serum prolactin like halopridol, reserpine, mytel- dopa, opiates and cimetidine; Maternal depression; History of previous depression; Inverted nipple; Having absolute or relative contraindication for breast-feeding in the mother including diseases such as untreated TB, infection with HIV, CMV, herpes simplex virus and hepatitis and taking of radioactive drugs and illegal drugs during the breastfeeding period, such as methotrexate, lithium, cyclophosphamide, hydroxyurea, phencyclidine, phenidone, opiate substances and metronidazole; History of chronic disease in the mother

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

In this study, participants, assessor and data analyzer will be blinded from type of intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz Univercity of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East azerbaijan

City

Tabriz

Postal code

Approval date

2016-12-26, 1395/10/06

Ethics committee reference number

IR.TBZMED.REC.1395.1020

Health conditions studied

1

Description of health condition studied

prevention of neonatal jaundice and increasing the volum of breast milk

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Newborn’s bilirubin

Timepoint

Before intervention and sixth day after the intervention

Method of measurement

TCB

2

Description

Mother’s prolactin serum level

Timepoint

Next day after starting of the intervention and sixth day.

Method of measurement

Prolactin ELISA Kit

Secondary outcomes

1

Description

Volume of breast milk

Timepoint

Two hours after the last breastfeeding in the first and sixth day of intervention

Method of measurement

Syringe

2

Description

Satisfaction from breastfeeding status

Timepoint

After the end of intervention

Method of measurement

Satisfaction checklist

Intervention groups

1

Description
The intervention group will receive Metoclopramide tablet, 10 mg three times per day for five days
Category
Treatment - Drugs

2

Description
The control group will receive 10 mg placebo tablet three times per day for five days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Dr. Mojgan Mirghafourvand
Street address
Taleghani hospital, Rah ahan street, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Mohammadreza Rashidi
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Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan
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Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Tabriz 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

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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