

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The investigating of the prophylactic effect of Manna of Cotoneaster in neonatal jaundice

Protocol summary

Study aim

The purpose of this study is the investigating of prophylactic effect of Manna of Cotoneaster in management of neonatal hyperbilirubinemia. This study was performed on 444 neonate patients, who admitted into the rooming in Imam Khomeini Hospital, Sari, Iran. Informed consent will be obtained from mothers

Design

Randomization: using blocking method.

Settings and conduct

This study was performed on 444 neonate patients, who admitted into rooming in ward Imam Khomeini Hospital, Sari, Iran. Informed consent will be obtained from mothers. The Blind: To double-blind study, Manna of cotoneaster solution and placebo solution container similar appearance (provided by the laboratory of Sari Pharmacy Faculty) and the user, administer and appraiser of them do not know about it. After administration of cotoneaster, all neonate will assess by one neonatologist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All healthy neonate with breastfeeding are examined by doctor and weight is between 2.5 to 4 kg. Exclusion criteria: Babies with a genetic anomaly, Congenital, Intrauterine infection or jaundice within 24 hours of birth and mothers who are not satisfied and want to be excluded

Intervention groups

Intervention group: The amount of 1 g of cotoneaster per day is divided into 3 doses for 3 days. Control group: The neonate will receive placebo. The number of placebo drops per day is similar to the number of cotoneaster drops.

Main outcome variables

The bilirubin concentration measured in 3 sets (24 hours 48 hours and 72 hours after birth) and its number is recorded. The Meconium departure time controlled daily for three days after birth. The baby bilirubin concentration measured through the skin by bilirubin

test device. Then on the third day that neonatal follow up examination will be done, bilirubin concentration measured through the skin with the same device.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060128188N1**

Registration date: **2016-10-22, 1395/08/01**

Registration timing: **prospective**

Last update: **2019-05-02, 1398/02/12**

Update count: **3**

Registration date

2016-10-22, 1395/08/01

Registrant information

Name

Moloud Fakhri

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-11-06, 1396/08/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The investigating of the prophylactic effect of Manna of Cotoneaster in neonatal jaundice

Public title
Preventive effect of droplets on infant's jaundice

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Full-term baby (with gestational age 38-42 weeks) Birth weight 2.5-4 kg No postpartum complications Breastfeeding within the hour of birth Availability of parents for follow-up purposes PO tolerance by the infant (no nausea, vomiting or obstructive symptoms The absence of meconium contamination No need for CPR at birth No labor trauma
Exclusion criteria:
 Genetic and congenital abnormalities or intrauterine infections Jaundice within the first 24 hours of birth ABO or Rh incompatibility Presence of neonatal hemolytic process Neonates with bleeding and cephalohematoma Self-administration of Cotoneaster

Age
From **1 day** old to **14 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
 Target sample size: **444**
 More than 1 sample in each individual
 Number of samples in each individual: **3**
 Measuring Bilirubin

Randomization (investigator's opinion)
Randomized

Randomization description
Using blocking method

Blinding (investigator's opinion)
Double blinded

Blinding description
To double-blind study, cotoneaster solution and placebo solution container similar appearance and the user, administer and appraiser of them do not know about it. Bilirubin drop and placebo drops (drug and placebo) are provided by the laboratory of Sari Pharmacy Faculty.

Placebo
Used

Assignment
Parallel

Other design features

Using blocking method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran,Sari, Moalem square

City

Sari

Province

Mazandaran

Postal code

4847191971

Approval date

2015-04-08, 1394/01/19

Ethics committee reference number

IR.MAZUMS.REC.1394.1316

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

p59.9

ICD-10 code description

neonatal jaundice

Primary outcomes

1

Description

Added at 2017-06-11: Baby serum total bilirubin

Timepoint

Added at 2017-06-11: Every 24 hours for 3 days

Method of measurement

Added at 2017-06-11: Using a bilirubin test device (if a bilirubin is high, a bilirubin serum test will be performed based on the weight and age curve)

Secondary outcomes

1

Description

Require hospitalization and Length of hospitalization days

Timepoint

From discharge to 14 days after birth

Method of measurement

Follow up by phone from the baby's parents

2

Description

Added at 2017-06-18: Evaluation of side effects in case of Cotoneaster

Timepoint

Added at 2017-06-18: Every 24 hours for 3 days

Method of measurement

Added at 2017-06-18: Observation and complete check list

Intervention groups

1

Description

Intervention group: The amount of 1 g of cotoneaster per day is divided into 3 doses for 3 days.

Category

Treatment - Drugs

2

Description

Control group: The neonate will receive placebo. The number of placebo drops per day is similar to the number of cotoneaster drops

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sari Imam Khomeini Hospital

Full name of responsible person

Moloud Fakhri

Street address

Amir Mazandarani Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saiedi

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Sari

Province

Mazandaran

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Grant name

-

Grant code / Reference number

1394.1316

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for research of Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Azadbakht

Position

Ph.D of Farmacognosy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mrs Dr.Farhadi

Position

Neonatal Specialist

Latest degree

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Other areas of specialty/work

Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All information will be published in an article. Details of the data are available at the request of the journal publisher and upon obtaining permission from the corresponding author.

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