Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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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 ,Moalem square
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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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Position
Neonatal Specialist

Latest degree
Subspecialist

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.

When the data will become available and for how long
Data is available as an article as soon as the article is published with permission from the corresponding author.

To whom data/document is available
The data is provided as an article by the journal, and those who have access to the journal can use the data contained in the article, with the permission of the corresponding author.

Under which criteria data/document could be used
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From where data/document is obtainable
The data is available to the journal and is accessible by obtaining permission from the corresponding author.

What processes are involved for a request to access data/document
Data is available from the journal after publication of the article.

Comments