Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessment of the effect of Cotoneaster drops in management of neonatal hyperbilirubinemia: a clinical trial

Protocol summary

Study aim
therapeutic effect of the researcher-made cotoneaster drop on jaundice in infants undergoing phototherapy.

Design
The study population consists of all infants with jaundice. This study is done after getting parents' consent. The present randomized double-blind clinical trial is conducted among four groups of infants. The sample size is determined using mean difference formula as 50 infants in each group, making a total sample size of 200 infants. Conduct and randomization: Cotoneaster and placebo drops (medication and placebo) are produced by Sari Faculty of Pharmacology laboratory in similar bottles and packing. A computer software program is used to produce random numbers to allocate the medication and placebo to four groups.

Settings and conduct
Sari, Bu Alisina Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria include all breastfed term neonate weighing between 2500 and 4000 grams and present with jaundice. Exclusion criteria include having incompatible blood group (RH), suffering from fauvism, being preterm, needing blood transfusion, suffering from infection or being the case of hemolysis.

Intervention groups
Intervention group 1(Control): The neonate with jaundice and mother will receive a placebo. Intervention group 2: The neonate with jaundice and the mother both will receive cotoneaster drops Intervention group 3: The neonate with jaundice will receive cotoneaster drops and the mother will receive placebo. Intervention group 4: The neonate with jaundice will receive a placebo, and the mother will receive cotoneaster drops.

Main outcome variables
Baby serum total bilirubin, The incidence of complications arising from the use of Cotoneaster

General information

Reason for update

Acronym
-

IRCT registration information
IRCT registration number: **IRCT2016060428188N2**
Registration date: **2016-12-26, 1395/10/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-04-24, 1398/02/04**
Update count: **1**

Registration date
2016-12-26, 1395/10/06

Registrant information

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Name of organization / entity
Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Vice Chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date
2016-10-22, 1395/08/01

Expected recruitment end date
2018-01-05, 1396/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of the effect of Cotoneaster drops in management of neonatal hyperbilirubinemia: a clinical trial

Public title
The investigation of theraputic effect of Cotoneaster drops on neonatal hyperbiirubinemia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All term neonate who present with jaundice, whose weights are 2500 to 4000 gr and who are feeding with breast milk The neonate 1 to 14 days old

Exclusion criteria:
blood incompatibility; Rh incompatibility; Fauvism; immaturity; need for blood transfusions; infection; hemolysis.

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

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **200**
More than 1 sample in each individual
Number of samples in each individual: **3**
Measuring Bilirubin

Randomization (investigator's opinion)
Randomized

Randomization description
A computer software program is used to produce random numbers to allocate the medication and placebo to four groups

Blinding (investigator's opinion)
Double blinded

Blinding description
Group 1: The neonate with jaundice and the mother receive placebo. Group 2: The neonate with jaundice and the mother receive cotoneaster drops. Group 3: The neonate with jaundice receives cotoneaster drops and the mother receives placebo. Group 4: The infant with jaundice receives placebo and the mother receives cotoneaster drops.

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
Vice chancellor for research, Mazandaran University of Medical Sciences, Moalem square, Sari, Mazandaran

City
Sari

Province
Mazandaran

Postal code
4817845413

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, unspecified

Primary outcomes

1

Description
Baby serum total bilirubin

Timepoint
Every 24 hours for 5 days

Method of measurement
Laboratory test

Secondary outcomes

1

Description
Length of hospitalisation days

Timepoint
At the time of discharge

Method of measurement
From the time of admission to discharge

2

Description
Added at 2017-06-11: The incidence of complications arising from the use of Cotoneaster
Timepoint
Added at 2017-06-11: Every 24 hours for 5 days
Method of measurement
Added at 2017-06-11: Observation and complete check list

3

Description
Added at 2017-06-11: Evaluation of side effects in case of Cotoneaster
Timepoint
Added at 2017-06-11: Every 24 hours for 5 days
Method of measurement
Added at 2017-06-11: Observation and complete check list

Intervention groups

1

Description
Intervention group 1 (Control): The neonate with jaundice and mother will receive placebo. The neonate with jaundice will receive placebo drops per day is similar to the number of cotoneaster drops. The mother will receive number of placebo drops per day is similar to the number of cotoneaster drops
Category
Treatment - Drugs

2

Description
Intervention group 2: The neonate with jaundice and the mother both will receive cotoneaster drops. Mothers will receive 5 ml of cotoneaster drops every 8 hours for 5 days. Neonate will receive amount of 1 g of cotoneaster per day is divided into 3 doses until 5 days.
Category
Treatment - Drugs

3

Description
Intervention group 3: The neonate with jaundice will receive cotoneaster drops and the mother will receive placebo. The mother will receive number of placebo drops per day is similar to the number of cotoneaster drops. Neonate will receive amount of 1 g of cotoneaster per day is divided into 3 doses until 5 days.
Category
Treatment - Drugs

4

Description
Intervention group 4: The neonate with jaundice will receive placebo, and the mother will receive cotoneaster drops. The neonate will receive number of placebo drops per day is similar to the number of cotoneaster drops. Mothers will receive 5 ml of cotoneaster drops every 8 hours for 5 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini Hospital
Full name of responsible person
Roya Farhadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mazandaran University of Medical Sciences
Full name of responsible person
Dr Majid Saidi

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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, 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
Fharmacy Department, Mazandaran University of Medical Sciences
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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
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Under which criteria data/document could be used
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From where data/document is obtainable
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What processes are involved for a request to access data/document
Data is available from the journal after publication of the article.

Comments