

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 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 favism, 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

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 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 therapeutic effect of Cotoneaster drops on neonatal hyperbilirubinemia

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; Favism; 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

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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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Imam Khomeini Hospital, Amir Mazandarani Blv, Sari, Iran

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Recruitment center

Name of recruitment center

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Full name of responsible person

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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**

Pharmacy Department, Mazandaran University of Medical Sciences

Full name of responsible person

Mohammad Azadbakht

Position

Ph.D of Farmacognosy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Roya Farhadi

Position

Neonatal Specialist

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Subspecialist

Other areas of specialty/work

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Faculty of Medicine, Mazandaran University of Medical sciences

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Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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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

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