

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of the effect of Bilinaster drop in the management of neonatal hyperbilirubinemia

Protocol summary

Study aim

The present study aims to assess the therapeutic effect of the Bilinaster drop on jaundice in neonates undergoing phototherapy.

Design

The present study is a randomized double-blind clinical trial with parallel groups using the blocking method. The sample size is determined using the mean difference formula as 50 infants in each group, making a total sample size of 100 neonates. A computer software program is used to produce random numbers to allocate the medication and placebo to two groups.

Settings and conduct

The study setting will be in Bu Alisina Hospital in Sari. Adequate medication and placebo for each group will be placed in a special envelope marked with patient number and medication code. Thus, patients, doctor and assessor will have no knowledge of the nature of medication or group allocation. Infants will enter the present study according to inclusion criteria and receive their particular medications.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All term neonate with jaundice weighted between 2500 -4000 gr and fed with breast milk. Exclusion criteria include babies with the incompatibility of blood groups or RH, suffering from favism, being preterm, needing blood transfusion, hemolysis or infection

Intervention groups

Control group: The neonate with jaundice will receive placebo. The number of placebo drops per day is similar to the number of bilinaster drops. Intervention Group: The neonate with jaundice will receive Bilineaster drop which is manufactured by Sobhan Daru Company and is included manna of cotoneaster (Shire-khesht). Bilineaster drop is prescribed about 1 g manna per day (15 drop) that is divided into 3 doses and at most until 5 days .

Main outcome variables

Baby serum total bilirubin

General information

Reason for update

Complete the information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016091828188N3**

Registration date: **2017-06-13, 1396/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-03, 1399/02/14**

Update count: **1**

Registration date

2017-06-13, 1396/03/23

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

2017-03-21, 1396/01/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of the effect of Bilinaster drop in the management of neonatal hyperbilirubinemia

Public title
The investigation of therapeutic effect of Bilinaster drop on neonatal hyperbilirubinemia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All term neonate with jaundice weighted between 2500 -4000 gr and fed with breast milk
Exclusion criteria:
blood incompatibility or Rh incompatibility Fauvism immaturity need for blood transfusions hemolysis infection

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

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
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 two groups. Adequate medication and placebo for each group will be placed in a special envelope marked with patient number and medication code. Thus, patients, doctor and assessor will have no knowledge of the nature of medication or group allocation

Blinding (investigator's opinion)
Double blinded

Blinding description
For blinding in this trial, similarity of interventions in the two treatment groups under study was anticipated. The placebo was prepared in similar packages, with all the same physical and similar properties (in terms of color, odor, consistency, etc.). The amount of ingestion and the number of times a day was the same in both products. The only difference in these two products was the code inserted (numerical code) on the package and the corresponding box. As the mothers and prescriber

(nurse) and laboratory technician were not aware of the nature of these two products and the codes entered.

Placebo
Used

Assignment
Parallel

Other design features

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

2017-02-28, 1395/12/10

Ethics committee reference number

IR.MAZUMS.REC.1395.2647

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 hospitalization days

Timepoint

At the time of discharge

Method of measurement

From the time of admission to discharge

2

Description

The incidence of complications arising from the use of Cotoneaster

Timepoint

Every 24 hours for 5 days

Method of measurement

Observation and complete check list

3

Description

Evaluation of side effects in case of Cotoneaster

Timepoint

Every 24 hours for 5 days

Method of measurement

Observation and complete check list

4

Description

The frequency of defecation

Timepoint

Daily

Method of measurement

Examination

Intervention groups

1

Description

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

Category

Placebo

2

Description

Intervention group: The neonate with jaundice will receive Bilineaster drop which is manufactured by Sobhan Daru Company and is included manna of cotoneaster (Shire-khesht). Bilineaster drop is prescribed about 1 g manna per day (15 drop) that is divided into 3 doses and at most until 5 days .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Boo Ali Hospital

Full name of responsible person

Roya Farhadi

Street address

Boo Ali Hospital, Pasdaran Blv, Imam Squ, Sari, Mazandaran, Iran Mazandaran

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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

1395.2647

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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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Moloud Fakhri

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific inquiries

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Full name of responsible person

Roya Farhadi

Position

Neonatal Specialist

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Province

Mazandaran

Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available