Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 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 fauvism, 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

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Moloud Fakhri

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
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 theraputic effect of Bilinaster drop on neonatal hyperbiirubinemia

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 bilinaster 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
Fharmacy 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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Neonatal Specialist

Latest degree
Subspecialist

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Assistant professor

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Traditional Medicine

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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