

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of the effect of Bilinoeid drop on neonatal jaundice

Protocol summary

Study aim

Therapeutic effect of jaundice among infants undergoing phototherapy

Design

The present randomized double-blind clinical trial is conducted on two groups of infants; Group 1: The infant with jaundice receive placebo. The sample size is determined using mean difference formula as 50 infants in each group, making a total sample size of 100 infants.

Settings and conduct

Conduct and randomization: The study setting will be in Bu Ali Hospital in Sari. 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. Bilinoeid and placebo drops (medication and placebo) are provided by the laboratory of Sari Pharmacy Faculty.

Participants/Inclusion and exclusion criteria

Inclusion criteria: infants present with jaundice Exclusion criteria: incompatible blood group (RH), favism, preterm, needing blood transfusion, suffering from infection or being the case of hemolysis

Intervention groups

Control group: The infant with jaundice will receive placebo. Intervention Group: The infant with jaundice will receive Cotoneaster drop.

Main outcome variables

1. Baby serum total bilirubin 2. The frequency of defecation 3. Length of hospitalization days 4. The incidence of complications arising from the use of Cotoneaster

General information

Reason for update

Information editing

Acronym

IRCT registration information

IRCT registration number: **IRCT20160531028188N4**

Registration date: **2018-03-05, 1396/12/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-08, 1399/02/19**

Update count: **3**

Registration date

2018-03-05, 1396/12/14

Registrant information

Name

Moloud Fakhri

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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m.fakhri@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-08-23, 1397/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of Bilinoeid drop on neonatal jaundice

Public title

Effect of Bilinoeid drop on neonatal jaundice

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 All infants who present with jaundice with weight between 2500 -4000 gr
Exclusion criteria:
 Blood group 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
- Outcome assessor

Sample size
Target sample size: **100**

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.

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. Patients, doctor and assessor will have no knowledge of the nature of medication or group allocation. Bilinoeid and placebo drops (medication and placebo) are provided by the laboratory of Sari Pharmacy Faculty.

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, Moalem square, Sari, Mazandaran

City

Sari

Province

Mazandaran

Postal code

48178

Approval date

2015-04-08, 1394/01/19

Ethics committee reference number

IR.Mazums.REC.941316

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

neonatal total bilirubin

Timepoint

every 24 hour til 5 days

Method of measurement

lab 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

frequency of defecation

Timepoint

every 24 hour til 5 days

Method of measurement

observation

Intervention groups

1

Description

Intervention group: The neonate with jaundice will receives cotoneaster manna drop which is prescribed about 1 g manna per day that is divided into 3 doses (every 8 hour) and at most until 5 days.

Category

Treatment - Drugs

2

Description

Control group: The neonate with jaundice will receive placebo. The number of placebo drops per day is similar to the number of cotoneaster drops that is divided into 3 doses (every 8 hour) 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

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Sari

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+98 11 2233 0111

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mmfir@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeidi

Street address

Vice chancellor for research, Moalem square, Sari

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Grant name

Grant code / Reference number

941316

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Mohammad Azadbakht

Position

Ph.D of Farmacognosy

Latest degree

Ph.D.

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Science

Full name of responsible person

Roya Farhadi

Position

Neonatal Specialist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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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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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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