

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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)

###### Phone

+98 11 3336 7343

###### Email address

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

##### **City**

Sari

##### **Province**

Mazandaran

##### **Postal code**

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##### **Phone**

+98 11 2233 0111

##### **Email**

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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##### **Phone**

+98 11 3325 7230

##### **Email**

mmfir@yahoo.com

#### **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

##### **Street address**

Mazandaran University of Medical Sciences, 18th Km Khazar Abad Road, Sari

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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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Moloud Fakhri

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Traditional Medicine

**Street address**

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mmfir@yahoo.com

**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