Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of oral Ursodeoxycholic acid with phototherapy on indirect hyperbilirubinemia in glucose-6-phosphate dehydrogenase-deficient neonates

Protocol summary

Study aim

Determination the Effect of oral Ursodeoxycholic acid with phototherapy on indirect hyperbilirubinemia in glucose-6-phosphate dehydrogenase-deficient neonates

Design

Clinical trial with control group, with 3 parallel groups, single-blinded, and randomized

Settings and conduct

The neonates who admit to the neonatal ward, randomly assigned to intervention group one and two, will receive Ursodeoxycholic acid manufactured by Koushan-Farma Co., Tehran, soluted in breast milk with two different doses, by a nurse as open label. The control group will receive the same amount of breast milk as placebo. The neonatologist, who evaluates the outcome in three groups, is blind to the study groups.

Participants/Inclusion and exclusion criteria

The 2 to 14 days-old neonates whose total bilirubin levels are in the range of phototherapy according to the neonatal phototherapy curve and need to be hospitalized and have glucose 6-phosphate dehydrogenase deficiency (G6PD) after diagnostic investigation . Neonates requiring exchange transfusion do not enter the study

Intervention groups

1.Group 1: neonates receiving phototherapy and Ursodeoxycholic acid (10 mg / kg / day every 12 hours to 48 hours). 2.Group 2: neonates receiving phototherapy and Ursodeoxycholic acid (20 mg / kg / day every 12 hours to 48 hours). 3.Control group: neonates receiving phototherapy and placebo (breast milk equal to volume of diluted drug in milk for 48 hours

Main outcome variables

Mean of total serum bilirubin at 12, 24,48 and 72 hours after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091201002801N4**
Registration date: **2019-06-15, 1398/03/25**
Registration timing: **prospective**

Last update: **2019-06-15, 1398/03/25**
Update count: **0**

Registration date

2019-06-15, 1398/03/25

Registrant information

Name
Roya Farhadi
Name of organization / entity
Mazandaran University of Medical Sciences
Country
Iran (Islamic Republic of)
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rfarhadi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of oral Ursodeoxycholic acid with phototherapy on indirect hyperbilirubinemia in glucose-6-phosphate dehydrogenase-deficient neonates

Public title
Effect of oral Ursodeoxycholic acid on indirect jaundice of glucose-6-phosphate dehydrogenase-deficient neonates

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Exclusive breast fed neonates Neonates with age of 2-14 days Direct bilirubin less than 15% of total serum billirubin or less than 1.5 mg/dl Neonates weighing between 2500 to 4000 grams. Neonates with jaundice and glucose 6-phosphate dehydrogenase deficiency require admission and phototherapy.

Exclusion criteria:
Neonates with sepsis diagnosis Blood group or Rh incompatibility between mother and neonate Direct hyperbilirubinemia Major congenital anomalies Need to exchange transfusion at the time of admission previous use of drugs like phenobarbital or cotoneaster History of previous exchange transfusion Previous phototherapy Infants of diabetic mother Spherocytosis or elliptocytosis in peripheral blood smear Evidence of severe hemolysis, Retic≥5%

Age
From **2 days** old to **14 days** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization of individuals by use of table of random numbers

Blinding (investigator's opinion)
Single blinded

Blinding description
Neonatologist who will investigate the bilirubin level and will asses the outcome is blind about the study groups.

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, Moallem Square.

City
Sari

Province
Mazandaran

Postal code
4815733971

Approval date
2019-05-12, 1398/02/22

Ethics committee reference number
IR.MAZUMS.REC.1398.222

Health conditions studied

1

Description of health condition studied
Neonatal jaundice

ICD-10 code
P59.8

ICD-10 code description
Neonatal jaundice from other specified causes

Primary outcomes

1

Description
Mean total serum bilirubin level based on Mg/dl

Timepoint
12, 24, 48 and 72 hours after intervention

Method of measurement
With the Diazo method and the kits of Tehran Pars Azmoon Co.

Secondary outcomes

1

Description
The percentage of total serum bilirubin reduction to the initial bilirubin

Timepoint
24 hours after admission

Method of measurement
With the Diazo method and the kits of Tehran Pars Azmoon Co.

2

Description

Duration of phototherapy

Timepoint

At discharge time

Method of measurement

Phototherapy's timer to hour

3

Description

Duration of admission

Timepoint

At discharge time

Method of measurement

Patient's file observation and documantation

4

Description

Duration of intensive phototherapy

Timepoint

At discharge time

Method of measurement

Patient's file observation and documantation

5

Description

Need to exchange

Timepoint

During admission

Method of measurement

Patient's file observation and documantation

6

Description

Need to re-hospitalization after discharge

Timepoint

14 days of life

Method of measurement

Patient's file observation and documantation

7

Description

The necessary time in which, first total serum bilirubin level reaches to less than 10mg/d

Timepoint

During admission

Method of measurement

Patient's file observation and documantation

Intervention groups

1

Description

Intervention group 1: Neonates receiving phototherapy and Ursodeoxycholic acid (10 mg / kg / day every 12 hours to 48 hours). Ursodeoxycholic acid is a 300 mg capsule manufactured by Kushan Pharma Co., Tehran with generic name of Ursobil is given to the neonate with a specific dose solutes in 2 cc of breast milk .

Category

Treatment - Drugs

2

Description

Intervention group 2: Neonates receiving phototherapy and Ursodeoxycholic acid (20 mg / kg / day every 12 hours to 48 hours). Ursodeoxycholic acid is a 300 mg capsule manufactured by Kushan Pharma Co., Tehran with generic name of Ursobil is given to the neonate with a specific dose solutes in 2 cc of breast milk .

Category

Treatment - Drugs

3

Description

Control group: Neonates receiving phototherapy and placebo (breast milk).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Boo Ali-Sina Hospital

Full name of responsible person

Roya Farhadi

Street address

Pasdaran bulevard-Boo Ali-Sina Hospital

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dr.royafarhadi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeidi

Street address

Vice chancellor for research, Mazandaran University of Medical Sciences, Moallem Square.

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Province

Mazandaran

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4817844718

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+98 11 3324 1906

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msaeedi@mazums.ac.ir

Grant name

Grant code / Reference number

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
Roya Farhadi

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Yes - There is 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

Part of the data will be shared.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

Only available for people working in academic institutions

Under which criteria data/document could be used

Getting written permission for any use of data

From where data/document is obtainable

Sending message to Dr. Roya Farhadi by E-mail: dr.royafarhadi@gmail.com

What processes are involved for a request to access data/document

After E-mail, information is sent within a few days.

Comments