

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparative study on efficacy of ursodeoxycholic plus phototherapy with single phototherapy in the treatment of indirect hyperbilirubinemia of neonates

Protocol summary

Summary

The main goal in this study is to consider the efficacy of ursodeoxycholic plus phototherapy in the treatment of indirect hyperbilirubinemia of neonates in comparison with single phototherapy. 100 newborns will be enrolled in the study and will be randomly divided into two groups. Inclusion criteria: Birth weight between 2500 to 4000 g; Only breastfeeding; Gestational age between 38 to 41 weeks; Older than 3 days, total bilirubin between 14 to 20 mg/dL; direct bilirubin less than 2 mg/dL. Exclusion criteria: ABO and RH incompatibility; G6PD Deficiency; Direct hyperbilirubinemia; Septicemia; diseases leading to hyperbilirubinemia; Premature infants; Newborns of diabetic mothers. This is a double blind study namely both the subjects participating and the researchers will be unaware of medication type. The treatment group (n=50) will receive 10 mg/kg/day divided q12h ursodeoxycholic acid in addition to phototherapy, while the control group (n=50) will receive just phototherapy. Total bilirubin levels will be measured every 12 hours until reaching below 10mg/dL. Also, duration of phototherapy and hospitalization in both groups will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201611163127N3**
Registration date: **2016-12-31, 1395/10/11**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-12-31, 1395/10/11

Registrant information

Name

Mehrdad Mirzarahimi

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1551 0399

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mmirzarahimi@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ardabil University of Medical Sciences

Expected recruitment start date

2015-03-20, 1393/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study on efficacy of ursodeoxycholic plus phototherapy with single phototherapy in the treatment of indirect hyperbilirubinemia of neonates

Public title

efficacy of ursodeoxycholic plus phototherapy in the treatment of neonatal jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Birth weight between 2500 to 4000 g; Only breastfeeding; Gestational age between 38 to 41 weeks; Older than 3 days, total bilirubin between 14 to 20 mg/dL; direct bilirubin less than 2 mg/dL. Exclusion criteria: ABO and RH incompatibility; G6PD Deficiency; Direct hyperbilirubinemia; Septicemia; diseases leading to hyperbilirubinemia (including Crigler-Najjar syndrome, Gilbert's syndrome, hypothyroidism / hyperthyroidism, liver diseases, and); Premature infants; Newborns of diabetic mothers.

Age

From **3 days** old to **28 days** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomizing with Closed Packet Method

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ardabil University of Medical Sciences

Street address

Ardabil University of Medical Sciences, Daneshgah Street, Ardabil.

City

Ardabil

Postal code

5618985991

Approval date

2015-10-23, 1394/08/01

Ethics committee reference number

IR.ARums.REC.1394.88

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

P58, P59

ICD-10 code description

Neonatal jaundice due to other excessive haemolysis,
Neonatal jaundice from other and unspecified causes

Primary outcomes

1

Description

total bilirubin

Timepoint

on admission and every 12 hours after admission until discharge

Method of measurement

Blood sampling

2

Description

time duration in which bilirubin levels reaches to normal level

Timepoint

Continuously (from treatment beginning until bilirubin reach to normal levels)

Method of measurement

Timer

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

-

Intervention groups

1

Description

Intervention Group: Phototherapy (with 8-lamp Phototherapy unit made by Tousan Company; Tehran, Iran) along with 10 mg/kg/day divided q12h ursodeoxycholic acid (made by Dr. Adidbi Company; Tehran, Iran). The intervention for each patient will start since him/her hospitalization and will continue until him/her total bilirubin level reaches below 10mg/dL.

Category

Treatment - Drugs

2

Description

Control Group: Phototherapy (with 8-lamp Phototherapy unit made by Tousan Company; Tehran, Iran) along with water as placebo. The intervention for each patient will start since him/her hospitalization and will continue until him/her total bilirubin level reaches below 10mg/dL.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Hospital

Full name of responsible person

Shima Sarfarazi

Street address

Bu Ali Hospital, Saheli Street, Ardabil

City

Ardabil

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Shima Sarfarazi

Position

Medical Resident

Other areas of specialty/work

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Fax

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Email

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Web page address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Dr Shahram Habibzadeh

Street address

Ardabil University of Medical Science, Daneshgah Street, Ardabil

City

Ardabil

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences.

Full name of responsible person

Dr Mehrdad Mirzarahimi

Position

Pediatrics Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Shima Sarfarazi

Position

Medical Resident

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty