

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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

##### Email address

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

**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**

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Shima Sarfarazi

**Position**

Medical Resident

**Other areas of specialty/work**

**Street address**

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**City**

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**Postal code**

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-

**Person responsible for scientific inquiries**

**Contact**

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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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**Position**

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**Other areas of specialty/work**

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**Web page address**

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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*