

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison of the effect of adding oral ursodeoxycholic acid to phototherapy and phototherapy alone on indirect hyperbilirubinemia in term infants with G6PDd and ABO and Rh incompatibility - a randomized controlled clinical trial study

#### Protocol summary

##### Study aim

Determining and comparing the effect of oral ursodeoxycholic acid along with phototherapy and phototherapy alone on indirect hyperbilirubinemia in 3- to 10-day-old term infants with G6PDd and ABO and Rh incompatibility

##### Design

This research is a single-blind randomized clinical trial study with a control group of term infants with the mentioned risk factors who receive phototherapy only, randomization before starting the program using <https://www.sealedenvelope.com> software, taking into account 53 people in each 2 groups (Urso group, photo and phototherapy alone) will be done in blocks of 4

##### Settings and conduct

This research is a clinical trial study that will be conducted in 17 Shahrivar hospital in Rasht on 3-10 day term infants with risk factors

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: infants aged 3 to 10 days, birth weight: 2500 to 4000 grams, exclusive breastfeeding, gestational age: 37 to 41 weeks, total bilirubin 14 to 20 and direct is less than 1 mg/dl. Exclusion criteria: history of any neurological disease, children with a history of seizures, electrolyte imbalance related to chronic disease (measured by blood test), direct hyperbilirubinemia (measured by blood test), septicemia, diseases leading to hyperbilirubinemia (Crigler-Najjar syndrome, Gilbert syndrome, hyperthyroid, hypothyroid, liver diseases), babies with jaundice w/o ABO and Rh incompatibility and G6PDD, receiving IVIG, preterm infants and babies of diabetic mothers, obstruction of the bile ducts and babies who have 2 or more risk factors at once.

##### Intervention groups

3- to 10-day-old term infants with indirect hyperbilirubinemia with G6PDd and ABO and Rh

incompatibility who receive ursodeoxycholic acid at a dose of 10 mg per kilogram per day in two equal doses and phototherapy and the control group that receives phototherapy alone

##### Main outcome variables

Bilirubin level! duration of hospitalization

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130313012803N3**

Registration date: **2023-12-02, 1402/09/11**

Registration timing: **prospective**

Last update: **2023-12-02, 1402/09/11**

Update count: **0**

##### Registration date

2023-12-02, 1402/09/11

##### Registrant information

##### Name

Sadroddin Mahdipour

##### Name of organization / entity

Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 1324 6963

##### Email address

smb1355@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2023-12-06, 1402/09/15

**Expected recruitment end date**

2024-04-18, 1403/01/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of adding oral ursodeoxycholic acid to phototherapy and phototherapy alone on indirect hyperbilirubinemia in term infants with G6PDd and ABO and Rh incompatibility - a randomized controlled clinical trial study

**Public title**

Investigation of the effect of oral ursodeoxycholic acid drug in neonatal jaundice

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

parents' complete satisfaction with the presence of infants in the study infants aged 3 to 10 days birth weight: 2500 to 4000 grams exclusive breastfeeding gestational age: 37 to 41 weeks total bilirubin 14 to 20 and direct is less than 1 mg/dl

**Exclusion criteria:**

history of any neurological disease children with a history of seizures electrolyte imbalance related to chronic disease (measured by blood test), direct hyperbilirubinemia (measured by blood test) septicemia, diseases leading to hyperbilirubinemia (Crigler-Najjar syndrome, Gilbert syndrome, hyperthyroid, hypothyroid, liver diseases) babies with jaundice without ABO and Rh incompatibility and G6PDD receiving IVIG preterm infants babies of diabetic mothers obstruction of the bile ducts babies who have 2 or more of the mentioned risk factors at once

**Age**From **3 days** old to **10 days** old**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Participant

**Sample size**Target sample size: **106****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization will be done before the start of the program using the <https://www.sealedenvelope.com> software, considering 53 people in each 2 groups (Urso group, photo and phototherapy alone) in blocks of 4, and each of them are placed in a separate envelope according to the list obtained from the software and the

envelope will be sealed and will be given to a third party. If the patient comes and is eligible, the envelope will be opened and according to the desired sequence, without knowing the next treatment, the patient is treated.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The method of allocating children in two groups is based on quadruple random blocks. If the children meet the entry criteria, they will be placed in two groups A (Urso) and B (control). Before starting the study, this list is kept hidden in the children's research center in a sealed envelope. After starting the reading list, the children will be placed in two groups, A and B, that is, Urso and control. Random allocation will be done by a third person who is unaware of the study and the groups, and the researchers will not be involved in this matter.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Vice-Chancellor of Gilan University of Medical SciencesIR

**Street address**

Siadati St

**City**

Rasht

**Province**

Guilan

**Postal code**

4456678709

**Approval date**

2023-10-18, 1402/07/26

**Ethics committee reference number**

IR.GUMS.REC.1402.372

**Health conditions studied****1****Description of health condition studied**

Infant hyperbilirubinemia

**ICD-10 code**

E80

**ICD-10 code description**

Disorders of porphyrin and bilirubin metabolism

**Primary outcomes**

## 1

### **Description**

Bilirubin level

### **Timepoint**

The studied infants are checked for hyperbilirubinemia upon arrival and then at least once every 12-24 hours with a serum sample

### **Method of measurement**

BT3500 device and photometric method using 2 and 4 dichloroaniline (DCA)

## **Secondary outcomes**

## 1

### **Description**

Duration of hospitalization

### **Timepoint**

During the period of hospitalization of the infant, the pediatric resident visits her every 8 hours and examines her for possible complications

### **Method of measurement**

Examination by the pediatric resident

## 2

### **Description**

Drug side effects

### **Timepoint**

During the period of hospitalization of the infant, the pediatric resident visits her every 8 hours and examines her for possible complications

### **Method of measurement**

Examination by the pediatric resident

## **Intervention groups**

## 1

### **Description**

Intervention group: 3 to 10-day term infants with indirect hyperbilirubinemia with G6PDd and ABO and Rh incompatibility who receive ursodeoxycholic acid at a dose of 10 mg per kilogram per day in two equal doses along with phototherapy

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: 3 to 10-day term infants with indirect hyperbilirubinemia with G6PDd and ABO and Rh incompatibility receiving phototherapy alone

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

17 Shahrivar Hospital, Rasht

#### **Full name of responsible person**

Dr. Sadruddin Mehdipour

#### **Street address**

Siadati St

#### **City**

Rasht

#### **Province**

Guilan

#### **Postal code**

4456678709

#### **Phone**

+98 13 3336 9002

#### **Email**

Smb1355@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Rasht University of Medical Sciences

#### **Full name of responsible person**

Dr. Ramyar Farzan

#### **Street address**

Guilan University of Medical Sciences, Gas Square

#### **City**

Rasht

#### **Province**

Guilan

#### **Postal code**

4144444444

#### **Phone**

+98 13 3333 5820

#### **Email**

Research@gums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Rasht 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**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Dr. Sadruddin Mehdipour  
**Position**  
Neonatologist  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Siadati St  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
4456678709  
**Phone**  
+98 13 3336 9002  
**Email**  
Smb1355@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Dr. Sadruddin Mehdipour  
**Position**  
Neonatologist  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Siadati St  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
4456678709

### Phone

+98 13 3336 9002

### Email

Smb1355@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Rasht University of Medical Sciences  
**Full name of responsible person**  
Dr. Sadruddin Mehdipour  
**Position**  
Neonatologist  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Pediatrics  
**Street address**  
Siadati St  
**City**  
Rasht  
**Province**  
Guilan  
**Postal code**  
4456678709  
**Phone**  
+98 13 3336 9002  
**Email**  
Smb1355@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Due to ethical issues

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available