# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Evaluating the Effect of Ursodeoxycholic Acid on total bilirubin of neonate with neonatal indirect hyperbilirubinemia who have Glucose-6-phosphate dehydrogenase deficiency compare to control group

## Protocol summary


**Study aim**
The effect of Ursodioxycholic acide (UDCA) on indirect bilirubin reduction in neonatal hyperbilirubinemia has been shown in a few studies, therefore, we aimed to investigate the effect of this drug in neonates with Glucose 6 phosphate dehydrogenase deficiency (G6pd) which can induce severe indirect hyperbilirubinemia.

**Design**
This is a clinical trial study phase 3 in neonates with G6PD deficiency and hyperbilirubinemia which performs in two parallel groups receiving drug and placebo. The study is a triple blind, block randomized design. The sample size is calculated to be 50.

**Settings and conduct**
The study is carried out on neonates with neonatal jaundice who are G6PD deficient and are admitted to Zeinabiye and Hafiz Hospitals in Shiraz for phototherapy. The nurse who is responsible for providing the medication, the carers, the doctors, and the bilirubin test laboratory and the data analyzer are not aware of intervention type.

**Participants/Inclusion and exclusion criteria**
This study will be performed on neonates with G6PD who are admitted with the diagnosis of hyperbilirubinemia for phototherapy. Inclusion criteria: G6pd deficiency, exclusive breastfeeding, over one day old, total bilirubin above 14 mg / dL and below 20 mg / dL and direct bilirubin below 2 mg / dL Exclusion criteria: Blood maladaptation, cholestatic or hepatic disease or infection and septicemia or diabetic mother infant.

**Intervention groups**
The intervention group will receive oral drug of Ursodioxycholic acide10 mg/kg (2cc syrup/kg) daily divided into 2 doses every 12 hours. Dr. Obidi's 300 mg capsule is used for the preparation of the syrups of 300 mg in 60 ml water. At the same time intervals, the control group received the same volume placebo syrup. Both groups receive standard phototherapy.

**Main outcome variables**
Total bilirubin; median admission time; drug adverse effects (Nausea, vomiting, rash)


## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190604043813N2**
Registration date: **2020-03-31, 1399/01/12**
Registration timing: **prospective**

Last update: **2020-03-31, 1399/01/12**
Update count: **0**

**Registration date**
2020-03-31, 1399/01/12

**Registrant information**


**Name**
Hourvash Akbari Haghighinejad

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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+98 71 3647 4967

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hhaghighi@sums.ac.ir


**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-04-20, 1399/02/01

**Expected recruitment end date**
2020-10-22, 1399/08/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluating the Effect of Ursodeoxycholic Acid on total bilirubin of neonate with neonatal indirect hyperbilirubinemia who have Glucose-6-phosphate dehydrogenase deficiency compare to control group

**Public title**

The effect of Ursodeoxycholic Acid on neonatal jaundice

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Exclusive breastfeeding, Total bilirubin levels above 14 mg / dL and below 20 mg / dL, Direct bilirubin levels below 2 mg / dL. Age above 1 day Glucose 6 phosphate dehydrogenase deficiency Parent consent

**Exclusion criteria:**

Infection and septicemia Uunderlying disease such as heart and liver disease The diabetic mother Rh incompatibility

**Age**

From **1 day** old to **10 days** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **3**

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**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The block randomization list with block size of 4 generates by https://www.sealedenvelope.com/simple-randomiser/v1/lists.The sample size , size of blocks and study groups are given to the system, and the system determines the order of the blocks and the order in each block in a list. The drug and placebo are arranged in a box according to the list by a pharmacist and are given to one of the nurses responsible for the research to be given to the infants.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The drug and placebo which are prepared in syrup and are distinguishable by A and B labels will be arrange in a box according to the randomization list by the pharmacist who has no responsibility for patients care . The box will be given to a nurse who is unaware of the intervention type and she give the treatment in specified order . Caregivers, physicians, and the lab conducting the bilirubin test are not aware of the treatment. The results are compiled and analyzed by a statistician who is not aware of the intervention type.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of research of Shiraz Medical School

**Street address**

Family medicine department , Namazi Hospital, Zand street

**City**

Shiraz

**Province**

Fars

**Postal code**

7184983858

**Approval date**

2017-11-22, 1396/09/01

**Ethics committee reference number**

IR.SUMS.MED.REC.1396.94

## Health conditions studied

### 1

**Description of health condition studied**

Neonatal indirect hyperbilirubinemia

**ICD-10 code**

P59.8

**ICD-10 code description**

Neonatal jaundice from other specified causes

## Primary outcomes

### 1

**Description**

Total bilirubin

**Timepoint**

Every 24 hours until total bilirubin fall bellow 10 mg/dl

**Method of measurement**

Total bilirubin is measured by the diazo method.

## Secondary outcomes

### 1

**Description**
Median admission time
**Timepoint**
Once
**Method of measurement**
The number of hospitalization days

## Intervention groups

### 1

**Description**
Intervention group: The intervention group will receive oral drug of Ursodeoxycholic acid (UDCA) 10 mg/kg (2cc/kg) daily divided into 2 doses every 12 hours. Dr. Obidi's 300 mg capsule is used for the preparation of the syrups of 300 mg in 60 ml water. Both intervention and control groups receive standard phototherapy and the baby's eye and genitalia are covered. The drug is continued until the bilirubin level is below 10 mg /dl.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: At 12 hours intervals, the control group received the same volume placebo syrup (1cc/kg). Both groups receive standard phototherapy and the baby's eye and genitalia are covered. The placebo is continued until the bilirubin level is below 10 mg /dl.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Zeinabiye Hospital
**Full name of responsible person**
Mehrdad Rezaie
**Street address**
Sibuye Blvd.
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**Province**
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### 2

**Recruitment center**
**Name of recruitment center**
Hafez Hospital
**Full name of responsible person**
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Abivardi Blvd.
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Shiraz University of Medical Sciences
**Full name of responsible person**
Younos Ghasemi
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**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Shiraz 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**
Shiraz University of Medical Sciences
**Full name of responsible person**
Hourvash Akbari Haghighinejad
**Position**
Assistant Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Family Physician
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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**Full name of responsible person**
Hourvash Akbari Haghighinejad
**Position**
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**Latest degree**
Specialist
**Other areas of specialty/work**
Family Physician
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Zand street, Namazi hospital, Family medicine department
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7184983858
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+98 71 3647 4967
**Fax**
**Email**
hhaghighi@sums.ac.ir

## 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**
Not applicable
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
All data without name, protocol, and study report can be shared
**When the data will become available and for how long**
6 months after publication
**To whom data/document is available**
all people who request to access the documents
**Under which criteria data/document could be used**
With reference to the original study , data will be available for systematic review and meta-analysis.
**From where data/document is obtainable**
hhaghighi@sums.ac.ir
**What processes are involved for a request to access data/document**
request send via email mentioned above
**Comments**