# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 2026

## Investigating the effect of Ursodeoxycholic acid and Synbiotic versus isolated phototherapy on indirect hyperbilirubinemia in hospitalized neonates under phototherapy.

## Protocol summary

**Study aim**

Comparison of the effect of Ursodeoxycholic acid and Synbiotic versus isolated phototherapy on indirect hyperbilirubinemia in hospitalized neonates under phototherapy.

**Design**

The clinical trial with two groups (intervention and control), pragmatic, double-blind, randomized.

**Settings and conduct**

This study was conducted to evaluate the effect of Ursodoxicillic Acid and Cynthiabacteric therapy on isolated indirect hyperbilirubinemia in hospitalized infants undergoing phototherapy in Sabzevar, Iran. Clinical observant and participants will be unaware of how they are grouped. Patients will be randomly assigned to intervention group 1 (Ursodoxicillic Acid and phototherapy), intervention 2 (Synbiotic and phototherapy) and control (phototherapy). Evaluation of the response to treatment is performed using a flame photometer at the end of the second day after the intervention for each of the three groups.

**Participants/Inclusion and exclusion criteria**

Inclusion Criteria: Infants aged 2 to 14 days, with a serum bilirubin level between 14 and 25 mg/dl and direct bilirubin of less than 2 mg/dl, with reticulocyte count in the normal range, with no Hematoma cerebral and Caput succedaneum. Exclusion Criteria: Infants with low hemoglobin and positive glucose 6-phosphate dehydrogenase enzyme and Coombs tests, Infants who receive serum therapy, antibiotic therapy, and IV immunoglobulin (IVIG).

**Intervention groups**

First intervention group: Patients in this group are treated with Ursodoxicillic acid (Alborzdarou Pharmaceutical Company) 10 mg/kg daily with phototherapy for two days. Second intervention group: Patients in this group are treated with Synbiotics (Zisttakhmir company) 5 daily drops with phototherapy for two days. Control group: Patients in this group are treated only with phototherapy for two days.

**Main outcome variables**

Total Bilirubin

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20181006041252N9**
Registration date: **2019-01-26, 1397/11/06**
Registration timing: **prospective**

Last update: **2019-01-26, 1397/11/06**
Update count: **0**

**Registration date**

2019-01-26, 1397/11/06

**Registrant information**

**Name**

Mohammad Sahebkar

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 4401 8337

**Email address**

sahebkarm@medsab.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2019-01-30, 1397/11/10

**Expected recruitment end date**

2019-03-30, 1398/01/10

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the effect of Ursodeoxycholic acid and Synbiotic versus isolated phototherapy on indirect hyperbilirubinemia in hospitalized neonates under phototherapy.

**Public title**
Comparison of the therapeutic effect of Ursodeoxycholic acid and Synbiotic versus isolated phototherapy on indirect hyperbilirubinemia.
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Infants aged 2 to 14 days. Infants with a serum bilirubin level between 14 and 25 mg/dl and direct bilirubin of less than 2 mg/dl. Infants with reticulocyte count in normal range. Infants with no Hematoma cerebral and Caput succedaneum. Infants with gestational age greater than 37 weeks. Infants with birth weight more than 2500 grams. Infants without polycythemia (hematocrit over 65). Infants without underlying illness. Infants without exchange transfusion.
**Exclusion criteria:**
Infants with low hemoglobin and positive glucose 6-phosphate dehydrogenase enzyme and Coombs tests. Infants who receive serum therapy, antibiotic therapy, and IV immunoglobulin (IVIG). Infants with abnormal peripheral blood smear tests. Infants with septicemia, Crigler–Najjar syndrome, thyroid and liver diseases. Infants from diabetic mother. Infants with direct hyperbilirubinemia, blood type incompatibility, and RH.
**Age**
From **2 days** old to **14 days** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Participant
- Care provider

**Sample size**
Target sample size: **120**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization was conducted based on a permutation block by a statistical consultant using random allocation software and the output sequences A, B, and C are available to the researcher, Accordingly, 20 blocks were allocated to patients, in each block, 2 from A treatment group, 2 from the B treatment group, and 2 from the C treatment group were placed. Eventually, after completing the blocks group A was treated with Ursodeoxycholic acid and phototherapy, Group B treated with Synbiotic and phototherapy, and Group C only treated with phototherapy. First, we determine all sixsome modes in which two individuals are assigned to group A and two to group B, and two to group C. Then we assign one of the digits 1 to 90 to each of the sixsome combinations (which includes ninety modes). In the next step, we must randomly select 20 blocks of six and write their combinations in succession. For this we have to make 20 samplings with replacement from a six-member community; 20 times, choose a random number between 1 and 90 and this process will continue until the end of the sampling and the difference between the three groups will not exceed a maximum of three (half the size of the block).
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
Each person will be assigned a study code A, B, and C, which will only be known to the researcher of the type of groups. The clinical observant and the participants are unaware of the groups; somehow that when the patient is referred to a clinical observer, they only put the patients in groups on the basis of sequentially numbered, sealed, opaque envelopes containing the code and there is no information about the treatment given for each code as well as the participants who are infants with 2 to 14 days' old will be unaware of the type of treatment due to lack of neurodevelopment.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Sabzevar University of Medical Sciences
**Street address**
Sabzevar University of Medical Sciences, Tohid Blvd, Sabzevar city
**City**
Sabzevar
**Province**
Razavi Khorasan
**Postal code**
9617913114
**Approval date**
2019-01-13, 1397/10/23
**Ethics committee reference number**
IR.MEDSAB.REC.1397.094

## Health conditions studied

### 1

**Description of health condition studied**
Indirect Hyperbilirubinemia (Neonatal jaundice)
**ICD-10 code**
P58.9
**ICD-10 code description**
Neonatal jaundice due to excessive hemolysis, unspecified

## Primary outcomes

### 1

**Description**
Total bilirubin
**Timepoint**
At the beginning of the study (before the intervention), 12, 24 and 48 hours after starting the intervention.
**Method of measurement**
Flame photometry device

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
First intervention group: Patients in this group are treated with Ursodoxicillic acid (Alborzdarou Pharmaceutical Company) 10 mg/kg daily with phototherapy for two days.
**Category**
Treatment - Drugs

### 2

**Description**
Second intervention group: Patients in this group are treated with Synbiotics (Zisttakhmir company) 5 daily drops with phototherapy for two days.
**Category**
Treatment - Drugs

### 3

**Description**
Control group: Patients in this group are treated only with phototherapy for two days.
**Category**
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Heshmatiyeh hospital
**Full name of responsible person**
Elahe Babaie Zarch
**Street address**
Heshamatiyeh Hospital, Asadabady Ave., Sabzevar Town
**City**
Sabzevar
**Province**
Razavi Khorasan
**Postal code**
9613873136
**Phone**
+98 51 4401 1014
**Email**
Heshmatiyeh.h@medsab.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Sabzevar University of Medical Sciences
**Full name of responsible person**
Dr. Fereshte Ghorat
**Street address**
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
**City**
Sabzevar
**Province**
Razavi Khorasan
**Postal code**
9617913114
**Phone**
+98 51 4401 8319
**Email**
Drghorat@gmail.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Sabzevar 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**
Sabzevar University of Medical Sciences
**Full name of responsible person**
Dr. Mitra Aldaghi
**Position**
Assistant Professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Pediatrics
**Street address**
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
**City**
Sabzevar
**Province**
Razavi Khorasan
**Postal code**
9617913114
**Phone**
+98 51 4401 1604
**Email**
Aldaghim@medsab.ac.ir

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Sabzevar University of Medical Sciences
**Full name of responsible person**
Dr. Mitra Aldaghi
**Position**
Assistant Professor
**Latest degree**
Subspecialist
**Other areas of specialty/work**
Pediatrics
**Street address**
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
**City**
Sabzevar
**Province**
Razavi Khorasan
**Postal code**
9617913114
**Phone**
+98 51 4401 1604
**Email**
Aldaghim@medsab.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Sabzevar University of Medical Sciences
**Full name of responsible person**
Elahe Babaie Zarch
**Position**
Medical student
**Latest degree**
Medical doctor
**Other areas of specialty/work**
General Practitioner
**Street address**
Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town
**City**
Sabzevar
**Province**
Razavi Khorasan
**Postal code**
9617913114
**Phone**
+98 51 4401 8337
**Email**
elnazbz@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Undecided - It is not yet known if there will be a plan to make this available
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Not applicable
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Undecided - It is not yet known if there will be a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
Undecided - It is not yet known if there will be a plan to make this available