

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Investigating the efficacy of Ursodeoxycholic acid on indirect hyperbilirubinemia in neonates treated with phototherapy

#### Protocol summary

##### Study aim

Efficacy of Ursodeoxycholic acid in the treatment of indirect hyperbilirubinemia in neonates

##### Design

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

##### Settings and conduct

The aim of this study was to investigate the efficacy of Ursodeoxycholic acid in the treatment of indirect hyperbilirubinemia in neonates in the specialty clinic of Heshamateyeh Hospital in Sabzevar city. In this study, the clinical observant and participants will be unaware of how children are grouped. Children are randomly assigned to the intervention (Ursodeoxycholic acid capsule and phototherapy) and the control (phototherapy) group. The response to treatment will be evaluated by measuring total bilirubin levels at 12, 24, and 36 after starting the intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The Birth weight more than 2500 gr, Gestational age more than 37 weeks, The birthday more than 2 days and less than two weeks, The Total bilirubin level is 14-20 mg/dl and the direct bilirubin level is less than 2 mg/dl. No Septicemia, lack of Crigler-Najjar syndrome, Thyroid, and liver disease, lack of direct hyperbilirubinemia, Incompatibility of blood group and RH, lack of G6PD deficiency. Exclusion criteria: Parental dissatisfaction for any reason. The incidence of any side effects of Ursodeoxycholic acid, Infants from diabetic mother

##### Intervention groups

Intervention group: Patients in this group are treated by phototherapy and capsules of Urosobil (manufactured by Alborz Pharmaceuticals and dissolved in 10 cc infant milk) at 10 mg/kg daily for two days. Control group: Patients in this group only are treated by phototherapy for two days.

##### Main outcome variables

Total bilirubin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170719035178N2**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

##### Registration date

2019-02-10, 1397/11/21

##### Registrant information

##### Name

Mitra Aldaghi

##### Name of organization / entity

Sabzevar University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 514411071

##### Email address

aldaghim@medsab.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-12, 1397/07/20

##### Expected recruitment end date

2019-06-10, 1398/03/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Investigating the efficacy of Ursodeoxycholic acid on indirect hyperbilirubinemia in neonates treated with phototherapy

## Public title

Efficacy of Ursodeoxycholic acid in the treatment of indirect hyperbilirubinemia in neonates

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Birth weight more than 2500 gr Gestational age more than 37 weeks The birthday more than 2 days and less than two weeks The total bilirubin level is 14-20 mg/dl and the direct bilirubin level is less than 2 mg/dl No Septicemia lack of Crigler-Najjar syndrome lack of Thyroid disease lack of Liver disease lack of direct hyperbilirubinemia Incompatibility of blood groups and RH lack of G6PD deficiency Infants aged 2 to 14 days

### Exclusion criteria:

Parental dissatisfaction for any reason The incidence of any side effects of Ursodeoxycholic acid Infants from diabetic mother

## 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: **88**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Block randomization based on permutation. Accordingly, 22 blocks are allocated to patients, in each block 2 from A treatment group and 2 from the B treatment group were placed. Eventually, after completion of the blocks, group A is treated with Phototherapy and Ursodeoxycholic acid capsule and Group B is treated with Phototherapy.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Each person in the study will be assigned code A and B, that the researcher will only be known of the type of groups. The clinician and practitioner are unaware of the groups.

## 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

2018-10-09, 1397/07/17

#### Ethics committee reference number

IR.MEDSAB.REC.1397.042

## Health conditions studied

### 1

#### Description of health condition studied

Indirect Hyperbilirubinemia

#### ICD-10 code

P58.9

#### ICD-10 code description

Neonatal jaundice due to excessive hemolysis, unspecified

## Primary outcomes

### 1

#### Description

Total bilirubin

#### Timepoint

The time intervals for measuring total bilirubin levels are at the baseline (before the intervention), 12, 24, and 36 hours after starting treatment (phototherapy with or without Ursobil).

#### Method of measurement

Autoanalyzer devices

## Secondary outcomes

### 1

#### Description

Drug side effects

#### Timepoint

During the intervention at 12, 24, and 36 hours after intervention

#### Method of measurement

Clinical evaluation

## Intervention groups

### 1

#### Description

Intervention group: Patients in this group are treated by phototherapy and capsules of Urosobil (manufactured by Alborz Pharmaceuticals and dissolved in 10 cc infant milk) at 10 mg/kg daily for two days.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Patients in this group are treated by phototherapy for two days

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Heshmatiyeh hospital

##### Full name of responsible person

Najmeh Mehri

##### Street address

Heshmatiyeh Hospital, Asadabady Ave., Sabzevar Town

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9613873136

##### Phone

+98 51 4401 1014

##### Email

mehri.najmeh@yahoo.com

## 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

Mitrah Aldaghi

##### Position

Assistant Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Pediatrics

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Sabzevar University of Medical Sciences, Tohid Blvd., Sabzevar Town

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9617913114

##### Phone

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##### 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

Mitrah Aldaghi

##### Position

Assistant Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Pediatrics

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+98 514411071

**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**

Najmeh Mehri

**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**

9613873136

**Phone**

+98 51 4493 3565

**Email**

mehri.najmeh@yahoo.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**

No - There is not 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