

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

Heshamatiyeh 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

Street address

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

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+98 51 4411 1071

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

Street address

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

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913114

Phone

+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