Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Adjuvant Ursodeoxycholic Acid Therapy in Neonates Undergoing Phototherapy for Hyperbilirubinemia: A Randomized Controlled Trial

Protocol summary

Study aim

To evaluate the effect of adjunctive ursodeoxycholic acid on serum bilirubin reduction and duration of phototherapy in neonates with indirect hyperbilirubinemia.

Design

Single-blind, parallel-group randomized controlled trial with 1:1 allocation. Based on the study by Akefi et al., and considering a significance level of $\alpha = 0.05$ (type I error) and a power of $1-\beta = 0.95$, the required sample size was calculated to be 128 participants per group. Taking into account a 5% potential dropout rate, the final sample size was determined to be 134 participants per group.

Settings and conduct

Neonatal and NICU departments of hospitals affiliated with Shiraz University of Medical Sciences (Hafez, Namazi, and Zeinabieh). This study will be a single-blind trial. Due to the nature of the intervention, blinding of parents and the nursing staff administering the medication will not be feasible. physician and data analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age ≤30 days, gestational age ≥35 weeks, indirect hyperbilirubinemia requiring phototherapy, parental informed consent Exclusion Criteria: Direct hyperbilirubinemia, major congenital anomalies, severe liver disease, previous UDCA exposure, hemodynamic instability, immediate need for exchange transfusion

Intervention groups

Following informed parental consent, eligible neonates will be enrolled and randomly assigned to two groups. The intervention group will receive oral ursodeoxycholic acid (UDCA) at a dose of 10 mg/kg/dose twice daily in addition to intensive phototherapy, whereas the control group will receive intensive phototherapy alone.

Main outcome variables

Duration of phototherapy until discharge (hours)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260915071065N2**
Registration date: **2026-11-07, 1405/08/16**
Registration timing: **prospective**

Last update: **2026-11-07, 1405/08/16**
Update count: **0**

Registration date

2026-11-07, 1405/08/16

Registrant information

Name

Hamide Barzegar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3612 2218

Email address

hamide.barzegar@gmail.com

Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date

2027-11-22, 1406/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Adjuvant Ursodeoxycholic Acid Therapy in Neonates Undergoing Phototherapy for Hyperbilirubinemia: A Randomized Controlled Trial

Public title

Adjuvant Ursodeoxycholic Acid Therapy in Neonates Undergoing Phototherapy for Hyperbilirubinemia

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

Age ≤30 days Gestational age ≥35 weeks Indirect hyperbilirubinemia requiring phototherapy Parental informed consent

Exclusion criteria:

Hemodynamic instability Previous UDCA exposure Direct hyperbilirubinemia, Major congenital anomalies Severe liver disease Immediate need for exchange transfusion

Age

From **1 day** old to **30 days** old

Gender

Both

Phase

1-2

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **268**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation sequence will be generated using a permuted block randomization method with blocks of four, ensuring an equal distribution of participants between the intervention and control groups. All six possible block combinations (ABAB, BABA, AABB, BBAA, ABBA, and BAAB) will be used. A table of random numbers will be employed to determine the order of these blocks and create the final allocation list for 268 participants (67 blocks in total)

Blinding (investigator's opinion)

Single blinded

Blinding description

This study will be conducted as a single-blind trial. Due to the nature of the intervention, blinding of parents and the nursing staff administering the medication will not be feasible. However, the physician responsible for evaluating the outcomes will be blinded to group allocation to minimize assessment bias. In addition, the data analyst will also be blinded to the intervention groups during statistical analysis, using coded data to ensure objectivity.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Shiraz University of medical sciences, Zand street, Shiraz

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2026-05-06, 1405/02/16

Ethics committee reference number

IR.SUMS.REC.1405.154

Health conditions studied

1

Description of health condition studied

Hyperbilirubinemia

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Duration of phototherapy until discharge (hours)

Timepoint

6,12 ,24 ,36 and 48 hours after starting treatment

Method of measurement

Capillary sampling

Secondary outcomes

1

Description

Need for exchange transfusion

Timepoint

6,12 ,24 ,36 and 48 hours after starting treatment and comparing results with exchange transfusion chart

Method of measurement

Capillary sampling

Intervention groups

1

Description
Intervention group: Oral UDCA 10 mg/kg every 12 hours plus intensive phototherapy.
Category
Treatment - Drugs

2

Description
Control group: Receive phototherapy alone
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Hafez Hospitals
Full name of responsible person
Hamide Barzegar
Street address
Hafez Hospital, Chamran Boulevard, Shiraz
City
Shiraz
Province
Fars
Postal code
7194634786
Phone
+98 71 3612 8000
Email
hafezhospt@sums.ac.ir

2

Recruitment center
Name of recruitment center
Namazi Hospital
Full name of responsible person
Hamide Barzegar
Street address
Namazi Hospital, Namazi Square, Shiraz
City
Shiraz
Province
Fars
Postal code
7193613311
Phone
+98 71 3612 5000
Email
Nemazee_inf@sums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
Street address
Central Building of Shiraz University of Medical Sciences, Zand Street, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3230 5410
Email
info@sums.ac.ir
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
Hamide Barzegar
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Namazi Hospital, Namazi Square, Shiraz
City
Shiraz
Province
Fars
Postal code
7193613311
Phone
+98 71 3612 5000
Email

hamide.barzegar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hamide Barzegar

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Namazi Hospital, Namazi Square, Shiraz

City
Shiraz

Province
Fars

Postal code
7193613311

Phone
+98 71 3612 5000

Email
hamide.barzegar@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Hamide Barzegar

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

Street address
Namazi Hospital, Namazi Square, Shiraz

City
Shiraz

Province
Fars

Postal code
7193613311

Phone
+98 71 3612 5000

Email
hamide.barzegar@gmail.com

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
Information regarding the primary outcome will be made available. Other data may be provided upon request in a de-identified format to protect patient confidentiality.

When the data will become available and for how long
Immediately after publication of the article.

To whom data/document is available
people working in academic institutions

Under which criteria data/document could be used
Reputable academic institutions. The purpose and rationale for the data request will be reviewed at the time of the request, and access will be granted at the discretion of the investigators based on this assessment.

From where data/document is obtainable
Requests must be submitted via email. Hamide Barzegar hamide.barzegar@gmail.com

What processes are involved for a request to access data/document
The rationale and purpose of the request must be provided via email. If the request is approved, the available data will be provided within 48 hours.

Comments