Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A Comparative Study Of The Effect Of Clofibrate And Ursobil In Reducing Phototherapy Time For Neonatal Jaundice

Protocol summary

Study aim
To Compare the Effectiveness of Clofibrate and Ursobil in Reducing the Duration of Phototherapy and Total Serum Bilirubin Levels in Term Neonates With Unconjugated Hyperbilirubinemia.

Design
A Phase 3, Single Blind, Randomized, Two Arm Parallel Group Clinical Trial in 70 Term Neonates With Unconjugated Hyperbilirubinemia. Participants Will Be Randomized in a 1:1 Allocation Ratio Using Balanced Block Randomization.

Settings and conduct
This Study Will Be Conducted in the Neonatal Ward of Imam Khomeini Hospital, Ilam, Iran. Eligible Neonates Will Be Randomly Allocated to Two Intervention Groups After Obtaining Informed Consent From Their Parents. All Neonates Will Receive Standard Phototherapy and Will Be Followed Until Discharge and 48 Hours After Discharge.

Participants/Inclusion and exclusion criteria
Term Neonates (37–42 Weeks); Birth Weight 2500–4000 g; Age 2–10 Days; Non-Hemolytic Unconjugated Hyperbilirubinemia; Exclusively Breastfed; Candidate For Phototherapy Per AAP Guidelines. Prior Medication Or Phototherapy Before Enrollment; Major Congenital Anomaly; Underlying Maternal Or Neonatal Disease; Parental Refusal To Participate.

Intervention groups
Intervention Group 1: Phototherapy With Ursobil (UDCA) 15 Mg/kg/day, Orally In Two Doses Every 12 Hours; 300-Mg Capsule, Dr. Abidi, Tehran, Iran, Dissolved In Water. Continued From The Start Of Phototherapy Until Total Bilirubin Is Less Than 10 Mg/dL And Phototherapy Is Discontinued. Intervention Group 2: Phototherapy With Clofibrate 30 Mg/kg, Single Oral Dose, Zahravi, Tabriz, Iran. Continued From The Start Of Phototherapy Until Total Bilirubin Is Less Than 10 Mg/dL And Phototherapy Is Discontinued. Phototherapy Is Identical In Both Groups According To The AAP Protocol.

Main outcome variables
Duration of Phototherapy Until It Decreases to Below 10 mg/dL.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260718070242N1**
Registration date: **2026-08-31, 1405/06/09**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-31, 1405/06/09**
Update count: **0**

Registration date
2026-08-31, 1405/06/09

Registrant information

Name
Hajar Ansari Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

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hajar.ansari7984@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-08-06, 1405/05/15

Expected recruitment end date
2026-11-06, 1405/08/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparative Study Of The Effect Of Clofibrate And Ursobil In Reducing Phototherapy Time For Neonatal Jaundice

Public title

Effect Of Clofibrate And Ursobil On Reducing Phototherapy Duration In Neonatal Jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term Neonates With Gestational Age of 37 to 42 Weeks Birth Weight Between 2500 and 4000 g Age 2 to 10 Days Non-Hemolytic Unconjugated Hyperbilirubinemia Exclusive Breastfeeding Candidates for Phototherapy According to the American Academy of Pediatrics (AAP) Guideline

Exclusion criteria:

Previous Use of Medications Affecting Neonatal Jaundice Before Study Entry Previous Phototherapy Before Study Entry Presence of a Major Congenital Anomaly Lack of Parental Consent to Participate in the Study Presence of Maternal Diseases, Such as Eclampsia, Diabetes, Chorioamnionitis, or Gestational Hypertension.

Age

From **2 days** old to **10 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible Participants Will Be Randomly Allocated After Obtaining Informed Consent to Two Study Groups, the Ursobil Group and the Clofibrate Group, Using Balanced Block Randomization With a Block Size of 4 and a 1:1 Allocation Ratio. The Randomization Unit Will Be Each Neonate. The Randomization Sequence Will Be Generated Using Microsoft Excel, and Participants Will Be Allocated According to the Pre Generated Randomization Sequence.

Blinding (investigator's opinion)

Single blinded

Blinding description

This Study Will Be Conducted as a Single Blind Trial. After Obtaining Informed Consent, the Parents Will Be Informed About Their Neonate's Participation in the Study and the Existence of Two Treatment Groups, Ursobil and Clofibrate, but They Will Not Be Informed of Their Neonate's Allocation to Either Treatment Group. The Assigned Intervention Will Be Administered to the Neonate by the Healthcare Personnel Responsible for Medication Administration, and the Treatment Group Will Not Be Disclosed to the Parents. The Researcher, Treating Physician, and Healthcare Personnel Will Be Aware of the Group Allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ilam University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Ilam University of Medical Sciences Campus, Pazhohesh Boulevard, Bangenjab, Ilam

City

Ilam

Province

Ilam

Postal code

6939177143

Approval date

2026-06-23, 1405/04/02

Ethics committee reference number

IR.MEDILAM.REC.1405.071

Health conditions studied

1

Description of health condition studied

Neonatal Unconjugated Hyperbilirubinemia

ICD-10 code

P59.8

ICD-10 code description

Neonatal jaundice from other specified causes

Primary outcomes

1

Description

Duration of Phototherapy Until Total Serum Bilirubin Decreases to Less Than 10 mg/dL (Hours)

Timepoint

From the Initiation of Phototherapy Until Discontinuation of Phototherapy During Hospitalization

Method of measurement

The Duration of Phototherapy Will Be Recorded in Hours From the Initiation of Phototherapy Until Its

Discontinuation (When Total Serum Bilirubin Falls Below 10 mg/dL). Total Serum Bilirubin Will Be Measured Using the DCA Method (Prestige 24i, Japan) in the Laboratory of Imam Khomeini Hospital, Ilam.

Secondary outcomes

1

Description
Total Serum Bilirubin Level
Timepoint
Before Initiation of the Intervention and at 24, 48, and 72 Hours After Initiation of the Intervention.
Method of measurement
Total Serum Bilirubin Will Be Measured Using the DCA Method (Prestige 24i, Japan) and Recorded in mg/dL.

2

Description
Length of Hospital Stay
Timepoint
At Hospital Discharge
Method of measurement
The Duration of Hospital Stay From Admission to Discharge Will Be Recorded in Days From the Medical Record

3

Description
Recurrence of Neonatal Jaundice After Discharge
Timepoint
After Completion of the Intervention and 48 Hours After Discharge From the Hospital
Method of measurement
Recurrence of Jaundice Will Be Evaluated at the 48-Hour Follow-Up Visit Based on Clinical Examination and, If Required, Total Serum Bilirubin Measurement.

4

Description
Short-Term Adverse Effects of the Intervention
Timepoint
During the Intervention Until Discharge and 48 Hours After Discharge From the Hospital
Method of measurement
Adverse Effects Will Be Assessed Through Clinical Examination, Review of Medical Records, and Recording in a Researcher-Designed Checklist.

Intervention groups

1

Description
Intervention Group 1: Ursodeoxycholic Acid (UDCA) Will Be Administered Orally At A Dose Of 15 Mg/kg/day, Divided Into Two Equal Doses Every 12 Hours. Ursobil Is Available As 300-Mg Capsules Manufactured By Dr. Abidi Pharmaceutical Company, Tehran, Iran. The Capsule Will Be Dissolved In Water And Administered Orally To The Neonate. Ursobil Will Be Administered From The Initiation Of Phototherapy Until The Discontinuation Of Phototherapy. Phototherapy And Ursobil Administration Will Be Discontinued When The Total Serum Bilirubin Level Reaches Less Than 10 Mg/dL.
Category
Treatment - Drugs

2

Description
Intervention Group 2: Clofibrate At A Dose Of 30 Mg/kg Will Be Administered As A Single Oral Dose. The Clofibrate Is Manufactured By Zahravi Pharmaceutical Company, Tabriz, Iran, With Batch Number 218 And Registration Number 1228098598. Clofibrate Will Be Administered From The Initiation Of Phototherapy Until The Discontinuation Of Phototherapy. Phototherapy And Clofibrate Administration Will Be Discontinued When The Total Serum Bilirubin Level Reaches Less Than 10 Mg/dL.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Neonatal Ward, Imam Khomeini Hospital, Ilam, Iran
Full name of responsible person
Sajad Nourollahi
Street address
Imam Khomeini Hospital, Before Shahid Morteza Sadeh-Miri St., Ayatollah Heydari St., Ilam, Iran
City
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Province
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Postal code
6931975397
Phone
+98 84 3333 8255
Email
emamkhominihospital@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
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Street address
Research and Technology Deputy, Ilam University of Medical Sciences Campus, Pazhouhesh Blvd., Banganjab, Ilam, Iran
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vcr@medilam.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ilam 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
Ilam University of Medical Sciences

Full name of responsible person
Hajar Ansari Mehr

Position
Intern

Latest degree
A Level or less

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
Hajar Ansari Mehr

Position
Intern

Latest degree
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Position
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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
Undecided - It is not yet known if there will be a plan to make this available

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available