Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of the therapeutic effect of clofibrate on reducing prolonged indirect hyperbilirubinemia in term neonates

Protocol summary

Study aim

To evaluate the therapeutic effect of clofibrate on reducing prolonged unconjugated hyperbilirubinemia in term neonates

Design

This is a phase 2–3 randomized clinical trial with two parallel groups. Participants were randomly assigned using a random number table to either the intervention group (clofibrate + phototherapy) or the control group (phototherapy only). Due to the clear difference in interventions, blinding of participants and implementers was not feasible; however, the data analyst was blinded to group allocation. The analysis will be based on the comparison of treatment efficacy.

Settings and conduct

The study will be conducted at the pediatric clinic of Imam Khomeini Hospital in Ilam

Participants/Inclusion and exclusion criteria

Participants are term neonates (gestational age 37–42 weeks) with birth weight over 2500 grams, presenting with prolonged unconjugated neonatal jaundice and clinically stable condition. Inclusion criteria: term neonate, normal birth weight, prolonged unconjugated jaundice, no underlying disease, no pathological jaundice, no active infection, and written informed consent from parents. Exclusion criteria: presence of underlying disease, pathological jaundice, active infection, prematurity, low birth weight, need for exchange transfusion at admission, or lack of parental consent to participate in the study.

Intervention groups

In the intervention group, in addition to receiving phototherapy based on the standard protocol, neonates will receive a single oral dose of clofibrate at 50 mg per kilogram of body weight. In the control group, neonates will receive only phototherapy according to the standard protocol.

Main outcome variables

Changes in total serum bilirubin levels measured on days 3 , 5 and 7 after intervention; The first measurment is performed using Blood sampling and subsequent measurments using a transcutaneous device

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250722066600N1**
Registration date: **2025-08-18, 1404/05/27**
Registration timing: **registered_while_recruiting**

Last update: **2025-08-18, 1404/05/27**
Update count: **0**

Registration date

2025-08-18, 1404/05/27

Registrant information

Name

Ahmadreza Heidarynezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3222 7134

Email address

ahmadrezaheidarynezhad12@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-22, 1403/07/01

Expected recruitment end date

2025-09-22, 1404/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effect of clofibrate on reducing prolonged indirect hyperbilirubinemia in term neonates

Public title

Studying the effect of clofibrate on reducing prolonged jaundice in newborns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The neonate is full-term with gestational age between 37 and 42 weeks Jaundice persists beyond the 14th day of birth The neonate has no underlying pathological conditions such as Infection , Liver disorders , Hypothyroidism , Cholestasis , Hemolysis , G6PD deficiency , Blood group incompatibilities , metabolic disorders The neonate has normal birth weight Written informed consent is obtained from the parents

Exclusion criteria:

The neonate has an active infection The neonate has liver disease , cholestasis or metabolic disorders The neonate has blood group incompatibility or G6PD deficiency The neonate has hypothyroidism The neonate is preterm (less than 37 weeks of gestation) The neonate has low birth weight (Less than 2500 grams) Parents refuse to participate in the study Serum bilirubin level is high enough to require exchange transfusion

Age

From **14 days** old to **28 days** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were randomly assigned to groups using a random number table. The random sequence was generated by an independent individual not involved in data collection or analysis. The allocation sequence was kept confidential to minimize allocation bias.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the clear difference between the intervention and control groups (use of clofibrate in the intervention group and not in the control group), blinding of participants and care providers was not feasible. However, the data analyst was blinded to the group assignments, and allocation information was not disclosed until the completion of data analysis.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics comittee of Ilam University of Medical Sciences

Street address

Ilam University of Medical Sciences Campus , Pazhuhesh Blvd , Banganjab

City

Ilam

Province

Ilam

Postal code

6939177143

Approval date

2024-02-14, 1402/11/25

Ethics committee reference number

IR.MEDILAM.REC.1402.253

Health conditions studied

1

Description of health condition studied

Prolonged Indirect Hyperbilirubinemia in Term Neonates

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Total serum bilirubin level in term neonates with prolonged indirect hyperbilirubinemia

Timepoint

Before the Intervention on day 1 , and on days 3 , 5 and 7 after the intervention

Method of measurement

At the beginning of the study, bilirubin levels will be measured using serum (blood) samples. In subsequent follow-ups, transcutaneous bilirubin will be used for monitoring to reduce invasiveness. However, if transcutaneous bilirubin levels are elevated or approach therapeutic thresholds, or if there is clinical discrepancy, serum measurements will be repeated to ensure data accuracy.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: in this group , term neonates with prolonged Unconjugated Hyperbilirubinemia , recieves oral clofibrate at a dose of 50 mg/kg as a single dose. In addition , phototherapy is continued according to the standard protocol.
Category
Treatment - Drugs

2

Description
Control group: In this group , term neonates with prolonged unconjugated hyperbilirubinemia receive phototherapy according to standard protocol , with no additional medication.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital , Ilam
Full name of responsible person
Jasem mohammadi
Street address
Imam Khomeini Hospital , Ayatollah Heidari street
City
Ilam
Province
Ilam
Postal code
6931975397
Phone
+98 84 3333 4500
Email
emamkhominihospital@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Naser Abbasi
Street address
Ilam University of Medical Sciences campus , Pazhuhesh Blvd , Banganjab
City
Ilam
Province
Ilam
Postal code
6939177143
Phone
+98 84 3222 7134
Email
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
Ahmadreza Heidarynezhad
Position
Medical Student
Latest degree
A Level or less
Other areas of specialty/work
Medical student
Street address
Ashoura street , Ghaem street , Banghalan
City
Ilam
Province
Ilam
Postal code
6939155585
Phone
+98 84 3225 1569
Email
ahmadrezaheidarynezhad12@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Jasem Mohammadi

Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Ilam University of medaical sciences campus , Pazhuhesh Blvd , Banganjab
City
Ilam
Province
Ilam
Postal code
6939177143
Phone
+98 84 3222 7134
Email
jmohamadi@medilam.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Ahmadreza Heidarynezhad
Position
Medical Student
Latest degree
A Level or less
Other areas of specialty/work
Medical student
Street address
Ashoura street , Ghaem street , Banghalan
City
Ilam
Province
Ilam
Postal code
6939155585
Phone
+98 84 3225 1569
Email
ahmadrezaheidarynezhad12@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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Yes - There is 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
Not applicable
Title and more details about the data/document
The study protocol, statistical analysis plan, and final clinical trial report after study completion will be shared upon formal request and approval by the Ethics Committee.
When the data will become available and for how long
The data will be available for 6 months after the publication of the article
To whom data/document is available
Qualified researchers, Faculty members, graduate students, and related professionals in related fields
Under which criteria data/document could be used
Only for research projects and academic publications, with proper citation and adherence to research ethics. Commercial use is not allowed.
From where data/document is obtainable
Requests can be directed to the corresponding author via the email registered in the IRCT system.
What processes are involved for a request to access data/document
After receiving a formal request, the research team will review the request, and upon approval, the requested documents will be sent via email.
Comments