Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The effect of fenofibrate on term neonatal hyperbilirubinemia admitted to hospital

Protocol summary

Study aim
To determine the effect of oral fenofibrate on term neonatal hyperbilirubinemia admitted to hospital

Design
A single-center randomized controlled trial, parallel groups including 86 neonates enrolled between July 2019 and July 2020 with blinded outcome assessment, randomization by the Random Allocation software

Settings and conduct
Neonates with hyperbilirubinemia admitted to the Pediatric Hospital of Bandar Abbas from 2019 to 2020 with regard to the inclusion and exclusion criteria, entered the study after obtaining informed consent from their parents. The intervention group received 10 mg/dl fenofibrate dissolved in 5 ml of distilled water. Then, both groups received phototherapy. Total bilirubin was measured on admission (before treatment) and subsequently every 24 hours until discharge (bilirubin <10 mg/dl). All neonates were visited as outpatients within the first week post-discharge for potential drug complications. To avoid any confounding effect, phototherapy was performed using the same device, with the same lights, half-lives, color, and wavelength. Bilirubin was measured using the caffeine method via spectrophotometry. Results and outcomes were evaluated by the investigator blinded to the groupings.

Participants/Inclusion and exclusion criteria
Inclusion criteria: gestational age >=37 weeks, weight >=2500 g, 72 hours>= age <=7 days, 15>= total bilirubin <=20 mg/dl Exclusion criteria: hemolytic diseases (ABO or Rh incompatibility), direct hyperbilirubinemia >2 mg/dl, G6PD deficiency, any specific disease including infections, systemic diseases, cephalohematoma, bowel obstruction, asphyxia, congenital anomalies, or chromosomal abnormalities, phenobarbital intake before or after birth

Intervention groups
Intervention group: phototherapy + 10 mg/kg fenofibrate dissolved in 5 ml of distilled water Control group: phototherapy

Main outcome variables
Hospital length of stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201209049660N1**
Registration date: **2020-12-24, 1399/10/04**
Registration timing: **retrospective**

Last update: **2020-12-24, 1399/10/04**
Update count: **0**

Registration date
2020-12-24, 1399/10/04

Registrant information

Name
Babak Gharaei Poor Abasabadi

Name of organization / entity
Hormozgan University of Medical Sciences, Faculty of Medicine

Country
Iran (Islamic Republic of)

Phone
+98 76 3371 0370

Email address
babakgharaei59hums@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date

2019-07-23, 1398/05/01

Actual recruitment end date

2020-07-22, 1399/05/01

Trial completion date

2020-07-31, 1399/05/10

Scientific title

The effect of fenofibrate on term neonatal hyperbilirubinemia admitted to hospital

Public title

Effect of fenofibrate in the treatment of neonatal jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age >= 37 weeks Weight >= 2500 g Age >=72 hours and <=7 days Total bilirubin >=15 mg/dl and <=20 mg/dl

Exclusion criteria:

Hemolytic disease (ABO or Rh incompatibility) Direct hyperbilirubinemia >2 mg/dl G6PD deficiency Any specific disease including infections, systemic diseases, cephalohematoma, bowel obstruction, asphyxia, congenital anomalies, or chromosomal abnormalities History of phenobarbital intake before or after birth

Age

From **3 days** old to **7 days** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **86**

Actual sample size reached: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization using a randomization table generated by the Random Allocation Software

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the investigator, the care provider, and the outcome assessor are all the same individual who is blinded to the groupings of patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

Technology and Research Vice-chancellery, East Side of Payambar Azam Hospital, Bandar Abbas

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2019-07-07, 1398/04/16

Ethics committee reference number

IR.HUMS.REC.1398.109

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

P59

ICD-10 code description

Neonatal jaundice from other and unspecified causes

Primary outcomes

1

Description

Hospital length of stay

Timepoint

At the end of the study

Method of measurement

Patients' medical charts

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 10 mg/kg fenofibrate (20 mg/ml syrup, Sobhan Darou, Iran) dissolved in 5 ml of distilled water plus phototherapy

Category

Treatment - Drugs

2

Description

Control group: Only phototherapy

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Bandar Abbas Pediatric Hospital

Full name of responsible person

Babak Gharaei Poor Asadabadi

Street address

Bandar Abbas Pediatric Hospital, Imam Khomeini Blvd., Bandar Abbas

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7366579158

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+98 76 3366 6242

Email

babakgharaei59hums@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Technology and Research Vice-chancellery, Hormozgan University of Medical Sciences

Full name of responsible person

Nasrin Davari Dolatabadi

Street address

Technology and Research Vice-chancellery, East Side of Payambar Azam Hospital, Bandar Abbas

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n.davari@hums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Technology and Research Vice-chancellery, Hormozgan 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

Bandar Abbas Pediatric Hospital

Full name of responsible person

Babak Gharaei Poor Abasabadi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All collected data will be available after deidentification.

When the data will become available and for how long
Data will be available starting in 2022

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

Under which criteria data/document could be used
Eligible individuals will be able to use the data for pooled analysis.

From where data/document is obtainable
Via an email address: babakgharaei59hums@gmail.com to Dr. Babak Gharaei Poor Abasabadi

What processes are involved for a request to access data/document
Within a month of presenting a valid identification card

Comments