

# 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  $\geq 37$  weeks, weight  $\geq 2500$  g, 72 hours  $\geq$  age  $\leq 7$  days, 15  $\geq$  total bilirubin  $\leq 20$  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  $\geq$  37 weeks Weight  $\geq$  2500 g Age  $\geq$  72 hours and  $\leq$  7 days Total bilirubin  $\geq$  15 mg/dl and  $\leq$  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

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7366579158

**Phone**

+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

**City**

Bandar Abbas

**Province**

Hormozgan

**Postal code**

7919915519

**Phone**

+98 76 3333 7379

**Email**

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

**Street address**

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

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Bandar Abbas Pediatric Hospital

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Resident

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Bandar Abbas Pediatric Hospital

**Full name of responsible person**

Babak Gharaei Poor Abasabadi

**Position**

Resident

**Latest degree**

Medical doctor

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**Email**

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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**