

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison between the Effect of Fenofibrate and Clofibrate on Term Neonates with Hyperbilirubinemia

Protocol summary

Study aim

To compare the effect of fenofibrate versus clofibrate on serum bilirubin level in term neonates with hyperbilirubinemia

Design

A randomized clinical double blinded trial with two groups of 40 neonates (total 80 neonates) in fenofibrate and clofibrate groups

Settings and conduct

At Amirkola Children Hospital all term neonates admitted for phototherapy with hyperbilirubinemia randomly were assigned to two groups, fenofibrate and clofibrate. All neonates fed by their mother's milk. Fenofibrate (Sobhan Co., Iran) in liquid form (20 mg/ml) 10 mg/kg single oral dose in fenofibrate group and clofibrate (Zahravi Co., Iran) in liquid form (100 mg/ml) 100 mg/kg single oral dose was given to another group after the initiation of phototherapy. The serum bilirubin level was checked daily by biochemical kit (made in Iran) and they were discharged after reaching the serum bilirubin level to < 10 mg/dl.

Participants/Inclusion and exclusion criteria

Healthy term, otherwise normal neonates with hyperbilirubinemia

Intervention groups

Fenofibrate and clofibrate groups

Main outcome variables

The serum bilirubin level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190708044158N1**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

Registration date

2020-02-01, 1398/11/12

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-08, 1398/08/17

Expected recruitment end date

2020-02-08, 1398/11/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the Effect of Fenofibrate and Clofibrate on Term Neonates with Hyperbilirubinemia

Public title

Comparison between the Effect of Fenofibrate and Clofibrate on Term Neonates with Hyperbilirubinemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term neonates(37 weeks to 41 weeks and 6 days) that their ages are more than 72 hours. They were admitted for jaundice, total bilirubin serum more than 15 mg/dl. They were otherwise healthy. They did not receive therapy other than phototherapy.

Exclusion criteria:

Premature neonates IUGR infants Neonates with congenital anomaly Neonates with blood group and RH incompatibility Neonates with G6PD deficiency Neonates with history of maternal phenobarbital consumption Neonates with respiratory distress and signs and symptoms of sepsis

Age

From **3 days** old to **28 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The neonates were allocated using a table of random numbers. In a table composed of the numbers from zero to nine after closing eyes, we pointed on a number, then moved horizontally. The number from zero to four allocated to clofibrate group and the number from five to nine allocated to the fenofibrate group. This work was continued until the end of the sample size was achieved.

Blinding (investigator's opinion)

Double blinded

Blinding description

All participant neonates blindly allocated to each group, the researcher is not aware of group assignment, and also the statistician is kept blind about the results.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Sciences

Street address

Vice-chancellor for Research Technology Affairs,

Babol University of Medical Sciences, Ganjafroz Street

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Province

Mazandaran

Postal code

4717647745

Approval date

2019-11-03, 1398/08/12

Ethics committee reference number

IR. MUBABOL. HRI. REC. 1398. 219

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

Serum bilirubin level

Timepoint

Admission time, second day, third day, discharge time

Method of measurement

Spectrophotometric method with the biochemical kit (made in Iran)

Secondary outcomes

1

Description

Duration of need to phototherapy and hospital stay

Timepoint

From the time of admission until discharge

Method of measurement

Duration of time by hour

Intervention groups

1

Description

Fenofibrate group: single dose of oral fenofibrate (Sobhan Co., Iran) in liquid form, containing 20 mg/ml, with a dose of 10 mg/kg was given at the time of admission. Standard phototherapy treatment was done. All the babies fed by their own mothers milk. Serum bilirubin level was checked at least every day at Amirkola Children's Hospital laboratory (biochemical kit, Iran) and reported as mg/dl. After reaching the serum bilirubin level to less than 10 mg/dl, neonates were discharged from hospital.

Category

Treatment - Drugs

2**Description**

CClofibrate group: single dose of clofibrate (Zahravi Co., Iran) in liquid form, containing 100 mg/ml, with a dose of 100 mg/kg was given at the time of admission. Standard phototherapy treatment was done. All the babies fed by their own mothers milk. Serum bilirubin level was checked at least every day at Amirkola Children's Hospital laboratory (biochemical kit, Iran) and reported as mg/dl. After reaching the serum bilirubin level to less than 10 mg/dl, neonates were discharged from hospital.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amirkola Children's Hospital

Full name of responsible person

Mousa Ahmadpour-kacho

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

Reza Ghadimi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Mousa Ahmadpour-kacho

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Other areas of specialty/work
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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

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

The outcomes including the serum bilirubin level in two groups at the end of the trial .

When the data will become available and for how long

Six months after the publication of the paper.

To whom data/document is available

Now for the researcher at the scientific and academic centers.

Under which criteria data/document could be used

For using the data to answer the unsolved questions regarding the research.

From where data/document is obtainable

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What processes are involved for a request to access data/document

Sending an Email to the corresponding person, explaining the request, recognizing the applicant by the corresponding person ,then sending the data to him/her.

Comments

Person responsible for updating data

Contact

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