Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
Ghorban Mohammad Nazari Komeshtappeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3235 4953

Email address
gh.nazari@mubabol.ac.ir

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 Sciencese

Street address

Vice-chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street

City

Babol

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

Street address
No 19, Amirkola Children's Hospital

City
Babol

Province
Mazandaran

Postal code
4731741151

Phone
+98 11 3235 4951

Fax
+98 11 3234 0656

Email
mousa_ahmadpour@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Reza Ghadimi

Street address
Vice-chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street

City
Babol

Province
Mazandaran

Postal code
4717647745

Phone
+98 11 3219 9591

Fax
+98 11 3219 4727

Email
info@mubabol.ac.ir

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

Street address
No 19, Amirkola Children's Hospital, Amirkola

City
Babol

Province
Mazandaran

Postal code
4731741151

Phone
+98 11 3235 4951

Fax
+98 11 3234 0656

Email
mousa_ahmadpour@hotmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Mousa Ahmadpour-kacho

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Professor

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Fax

+98 11 3234 0656

Email

mousa_ahmadpour@hotmail.com

Person responsible for updating data

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Ghorban Mohammad Nazari Komeshtappeh

Position

Fellow

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

No 19, Amirkola Children's Hospital, Amirkola

City

Babol

Province

Mazandaran

Postal code

4731741151

Phone

+98 11 3235 4951

Fax

+98 11 3234 0656

Email

gh.nazari@mubabol.ac.ir

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

Mouasa Ahmadpour-kacho No 19, Amirkola Children's Hospital, Amirkola, Babol Cellphone: +989111122855 Tel. No: +98 1132354951, Email: mousa_ahmadpour@hotmail.com Fax: +981132340656

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