

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of oral fenofibrate on serum bilirubin level in term neonates with hyperbilirubinemia.

Protocol summary

Summary

Purpose: Evaluation of oral fenofibrate on serum bilirubin level in term neonates with hyperbilirubinemia all the newborns with an age of more than 72 hours that had been referred to Amirkola Children's Hospital (ACH) with serum bilirubin level more than 15 mg/dl have been considered as the case group and receive phototherapy according to the ACH phototherapy protocol, on the other hand newborn with serum bilirubin level more than 15 mg/dl have been considered as control group in both groups phototherapy were done according to the ACH phototherapy protocol bilirubin was checked by diazo (photometr) method by darman farazkave kits company, Iran. If we considered the impact factor 0.6 for during of admission and 60 percent ability test, the sample size was calculated for each group 40 neonates. The study is double blinded and performed via a random number table. Study phases are as clinical research and done in one center. The intervention group receive 10 mg/dl fenofibrate, but the control group receive nothing, other than phototherapy. Inclusion criteria: full term newborns with an age of more than 72 hours and serum bilirubin level more than 15 mg/dl. Exclusion criteria: preterm neonates, IUGR, sepsis, respiratory distress. Intervention: fenofibrate administration. Primary outcome: determination of serum bilirubin level. The secondary outcome: duration of phototherapy, unresponsive to phototherapy, severe hyperbilirubinemia and need to exchange in two groups.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017081635732N1**

Registration date: **2017-10-17, 1396/07/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-17, 1396/07/25

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Babol university of medical sciences

Expected recruitment start date

2017-09-22, 1396/06/31

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of oral fenofibrate on serum bilirubin level in term neonates with hyperbilirubinemia.

Public title

Effect of oral fenofibrate on serum bilirubin level in term neonates with hyperbilirubinemia.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: full-term newborns, with of age of more than 72 hour and serum bilirubin level more than 15 mg/dl. Exclusion criteria: Preterm infants, IUGR, Congenital anomaly, Respiratory distress, sepsis.

Age

From **1 day** old to **28 days** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Non-Communicable Pediatric Diseases Research Center, No 19, Amirkola Children's Hospital, Amirkola,

City

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Postal code

47317-41151

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

MUBABOL.HRI.REC.1396.36

Health conditions studied

1

Description of health condition studied

Hyperbilirubinemia

ICD-10 code

P59.9

ICD-10 code description

Physiological jaundice (intense)(prolonged) NOS

Primary outcomes

1

Description

Serum bilirubin's level

Timepoint

Total serum bilirubin level measured at the time of admission, daily during the hospitalization and at the time of the discharge.

Method of measurement

Bilirubin was checked by diazo (Photometr) method by farazkave therapy kits that producing in Iran.

Secondary outcomes

1

Description

Duration phototherapy unresponsive to phototherapy, severe hyperbilirubinemia need to exchange.

Timepoint

Time of admission and time of discharge

Method of measurement

Auto analyzer

Intervention groups

1

Description

Intervention group: The intervention group receive Fenofibrate 10mg/kg.

Category

Treatment - Drugs

2

Description

control group: The control group receive placebo.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkola Children's Hospital

Full name of responsible person

Maryam Vafaeinezhad

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

Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences

Full name of responsible person

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Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences, Ganjafroz Street, Babol, Mazandaran Province, IR Iran

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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

Vice- Chancellor for Research Technology Affairs, Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Amirkola Children's Hospital

Full name of responsible person

Dr Maryam Vafaeinezhad

Position

Pediatrician

Other areas of specialty/work**Street address**

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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)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty