Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 refered 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 cheked 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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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
Babol
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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Amirkola, Babol

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
Dr Ali Akbar Moghaddamnia
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Babol
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
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Person responsible for updating data

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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