Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The effect of fenofibrate on the prevention of neonatal hyperbilirubinemia in mothers with O type blood group

Protocol summary

Study aim
Investigating the effect of fenofibrate on prevention of neonatal hyperbilirubinemia in mothers with O type blood group

Design
A randomized single-blind study with two groups of 60 neonatal (120 neonatal in total) in fenofibrate and control groups. Random number table was used for randomization.

Settings and conduct
The study is a clinical trial and is performed in two centers of Shahid Yahya Nejad and Amirkola Children's Hospital. A cord blood sample is taken from the neonate and the neonate is included in the study if he or she has blood type A or B. The neonatal are then randomly divided into two groups of 60 people. After getting consent from parents and after breastfeeding in the first hour, the content of fenofibrate capsules is given to the case group, at a dose of 10 mg per kg as a single dose, orally and in solution distilled water. Bilirubin levels will be measured using a dermal bilirubin meter at 12, 24, 48 and 72 hours after birth for both groups. The study is single blind and is done through tables of random numbers.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Term neonatal (37 weeks to 41 weeks and 6 days), born with blood type A or B from mothers with O blood type, and fathers with A, B or AB blood type, without congenital anomalies and birth trauma and also resuscitation at birth, born by elective cesarean section that did not receive induction before delivery, and without Rh incompatibility; Output criteria: neonatal using other medicines such as: phenobarbital, outpatient medicines, etc., neonatal with G6PD enzyme.

Intervention groups
Intervention group: Fenofibrate is given 10 mg per kg in a single dose. Control group: no medicine is given.

Main outcome variables
Transcutaneous bilirubin level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200822048473N1**
Registration date: **2020-08-24, 1399/06/03**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-24, 1399/06/03**
Update count: **0**

Registration date
2020-08-24, 1399/06/03

Registrant information

Name
Seddighe norouzian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 11 3230 0538

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yazdi.mohammad@nit.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-24, 1399/06/03

Expected recruitment end date
2021-08-25, 1400/06/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of fenofibrate on the prevention of neonatal hyperbilirubinemia in mothers with O type blood group

Public title
The effect of fenofibrate on the prevention of neonatal hyperbilirubinemia in mothers with O type blood group
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Term neonatal (37 weeks to 41 weeks and 6 days) Neonatal with blood type A or B from mothers with positive O blood type and fathers with A, B or AB blood types Without congenital anomalies, birth trauma and history of resuscitation at birth Neonatal born by elective cesarean section who did not receive induction before delivery Rh incompatibility
Exclusion criteria:
Age
From **1 day** old to **28 days** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical trial study, by simple randomization method and using table of random numbers, 120 patients are divided into two study groups and receive the intervention of the corresponding group.
Blinding (investigator's opinion)
Single blinded
Blinding description
The sampler and the researcher, as the person prescribing the medicine, are aware of the study process, but the neonate is not aware of the study process.
Placebo
Not used
Assignment
Other
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
Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran
City
Babol
Province
Mazandaran
Postal code
4717647745
Approval date
2020-08-10, 1399/05/20
Ethics committee reference number
IR.MUBABOL.REC.1399.229

Health conditions studied

1

Description of health condition studied
Neonatal jaundice
ICD-10 code
P58
ICD-10 code description
Neonatal jaundice due to other excessive hemolysis

Primary outcomes

1

Description
Transcutaneous bilirubin level
Timepoint
Measurement of transcutaneous bilirubin levels at the end of 12, 24, 48 and 72 hours after birth and at the time of admission, in both control and fenofibrate groups
Method of measurement
Transcutaneous bilirubin meter

Secondary outcomes

1

Description
Jaundice leading to hospitalization
Timepoint
During hospitalization
Method of measurement
Blood test

2

Description
Duration of phototherapy
Timepoint
During hospitalization
Method of measurement
Duration in days

3

Description
The rate of severe jaundice
Timepoint
During hospitalization

Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Fenofibrate is given as a single dose of 10 mg per kg.
Category
Prevention

2

Description
Control group: No medicine is given.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Yahyanejad hospital
Full name of responsible person
Seddighe Nourozian
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2

Recruitment center
Name of recruitment center
Amirkola children's hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Seddighe Norouzian
Position
Resident
Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available