

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)

Phone

+98 11 3230 0538

Email address

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

+98 11 3234 0656

Email

norouzian88s@gmail.com

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

Street address

Shahid Mostafa Khomeini Ave., Modarres Street, Babol

City

Babol

Province

Mazandaran

Postal code

4717647745

Phone

+98 11 3222 3594

Email

norouzian88s@gmail.com

2

Recruitment center

Name of recruitment center

Amirkola children's hospital

Full name of responsible person

Seddighe Norouzian

Street address

Darolshafa Ave., Imam Khomeini Street, Amirkola, Babol

City

Babol

Province

Mazandaran

Postal code

4731741151

Phone

+98 11 3235 4951

Fax

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

Street address

Babol University Of Medical Sciences, Ganj Afrooz Street, Babol, Mazandaran, Iran

City

Babol

Province

Mazandaran

Postal code

4717647754

Phone

+98 11 3219 0958

Email

rezaghadimi@yahoo.com

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

Other areas of specialty/work

Pediatrics

Street address

Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran.

City

Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3219 2832
Fax
+98 11 3219 2959
Email
norouzian88s@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
Seyedeh Zahra akbarian Rad
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
Babol University of Medical Sciences, Ganjafrooz
Street, Babol, Mazandaran ,Iran
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3219 2832
Email
zhr_akbarian@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Seddighe Norouzian
Position
Resident
Latest degree
Specialist
Other areas of specialty/work
Pediatrics
Street address
Babol University of Medical Sciences, Ganjafrooz
Street , Babol , Mazandaran ,Iran.
City
Babol
Province
Mazandaran
Postal code
4717647745
Phone
+98 11 3219 9592
Email
norouzian88s@gmail.com

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