Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effect of adding a single dose of fenofibrate to phenobarbital in the treatment of prolonged neonatal jaundice with phenobarbital alone

Protocol summary

Study aim

The aim of this study was to evaluate the simultaneous effect of single dose of fenofibrate and phenobarbital against phenobarbital alone on prolonged jaundice of mature (full term) neonates.

Design

Clinical trial with control group, with parallel groups, without blinding, simple randomized, phase 3 on 60 patients. Excel software rand function was used for randomization.

Settings and conduct

Sixty infants who referred to Dr. Golshan's office were selected from a statistical population of eligible individuals in a consecutive manner and then randomly (using a random number table) were divided into two groups of 30 each. After obtaining parental permission, the neonates were divided into two groups: phenobarbital or control group (n = 30) and phenobarbital + fenofibrate group (n = 30). Total bilirubin was measured in both groups during referral and 7 days after treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All full-term infants (gestational age between 37 to 41 weeks), age between 14 to 40 days, weighing between 2500 to 4000 grams, Breastfed, containing total bilirubin 10 to 20 mg/dl, no Symptoms of hemolysis in a blood test, without symptoms of infectious disease or any abnormality Conditions of absence: In case of clinical or laboratory signs of infection, any abnormalities, dehydration, glucose-6-phosphate deficiency, positive Combs test, history of phenobarbital administration by mother or infant, indirect bilirubin more than 2 mg/dL Total bilirubin more than 20 mg per deciliter

Intervention groups

The control group is given phenobarbital tablets for 5 days (first day 10 mg/kg then 5 mg/kg). The intervention group is given a single dose of fenofibrate (10 mg/kg) with phenobarbital tablets for 5 days.

Main outcome variables

Total bilirubin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201118049433N1**
Registration date: **2020-12-10, 1399/09/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-10, 1399/09/20**
Update count: **0**

Registration date

2020-12-10, 1399/09/20

Registrant information

Name

Mohammad Golshan Tafti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3725 8060

Email address

mgolshan035@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-09, 1399/05/19

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of adding a single dose of fenofibrate to phenobarbital in the treatment of prolonged neonatal jaundice with phenobarbital alone

Public title

The effect of adding fenofibrate to phenobarbital in the treatment of prolonged neonatal jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Infants who are full-term (gestational age between 37 and 41 weeks) All infants between the ages of 14 and 40 days All infants weighing between 2500 and 4000 grams Infants who are breastfed All infants with total bilirubin 10 to 20 mg/dL Infants who show no signs of hemolysis on a blood test Infants who do not have symptoms of an infectious disease or any abnormality

Exclusion criteria:

Infants who are dehydrated Infants who test positive for Coombs Infants with indirect bilirubin more than 2 mg/dL

Age

From **14 days** old to **40 days** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, we used a simple randomization method. The number of 60 eligible infants who referred to the neonatal clinic consecutively was numbered from 01 to 60 in order of referral time. Then the rand function of Excel software was used for randomization. The neonates were divided into two groups of 30 A(phenobarbital or control group) and B(fenofibrate+ phenobarbital group).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University of Yazd

Street address

Research unit, Ali Ibn Abitaleb Medical School, Islamic Azad University Of Yazd, Shohada Gomnam Boulevard, Safaeieh

City

Yazd

Province

Yazd

Postal code

8916877318

Approval date

2020-08-09, 1399/05/19

Ethics committee reference number

IR.IAU.YAZD.REC.1399.035

Health conditions studied

1

Description of health condition studied

Prolonged neonatal jaundice

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Total bilirubin

Timepoint

At the beginning of the study (before the intervention) and 7 days after the start of the procedure

Method of measurement

Bilirubin meter

Secondary outcomes

empty

Intervention groups

1

Description

In this group, phenobarbital tablets with a dose of 10 mg/kg on the first day and then with a dose of 5 mg/kg until the fifth day, are given orally daily.

Category

Treatment - Drugs

2

Description

Intervention group: In this group, a single dose of

fenofibrate capsules at a dose of 10 mg/kg with phenobarbital tablets at a dose of 10 mg/kg on the first day and then at a dose of 5 mg/kg until the fifth day, is given orally daily.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Mohammad Golshan Tafti's office

Full name of responsible person
Dr. Mohammad Golshan Tafti

Street address
Dr. Golshan office, Golchin Ave., Taleghani Blvd., Yazd Town

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8915145653

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mgolshan035@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Seyed Mohammad Reza Mortazavizadeh Yazdi

Street address
Research unit, Ali Ibn Abitaleb Medical School, Islamic Azad University Of Yazd, Shohada Gomnam Boulevard, Safaeieh

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Mohammad Golshan Tafti

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Pediatrics

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Dr. Golshan office, Golchin Ave., Taleghani Blvd., Yazd Town

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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