

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of clofibrate and Phenobarbital on bilirubin level, hospitalization and phototherapy period in icteric non hemolytic newborns

Protocol summary

Summary

The effects of adding either Clofibrate or Phenobarbital on bilirubin level hospitalization and phototherapy period are evaluated in icteric non-hemolytic newborns. Inclusion criteria: icteric non-hemolytic; term neonates; indirect icter; breast feeding only. Exclusion criteria: Infants with hemolytic icter; premature neonates; direct icter; formula feeding. 90 neonates admitted at Hajar hospital; Shahrekord, at the year 2012 will be included in the study. They will be divided in three groups each with 30 neonates. Two groups receive 100 mg /kg Clofibrate or 5 mg /kg Phenobarbital orally as single dose on arrival, in addition to phototherapy. The control group receives phototherapy only. Serum bilirubin level is measured at reception and 12, 24, 48 and 72 hours after beginning of drug therapy. These values together with hospitalization and phototherapy period are compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202199073N1**

Registration date: **2012-07-05, 1391/04/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-07-05, 1391/04/15

Registrant information

Name

Majid Hamidi

Name of organization / entity

Shahrekord University of Medical Science

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellery for Research, Shahrekord university of medical science, Iran

Expected recruitment start date

2012-04-03, 1391/01/15

Expected recruitment end date

2012-06-04, 1391/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of clofibrate and Phenobarbital on bilirubin level, hospitalization and phototherapy period in icteric non hemolytic newborns

Public title

Evaluating the effect of drug therapy on neonatal icter

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Parents permission; Infants with non-hemolytic icter; term neonates (37-42 weeks age); birth weight 2/5- 4kg; breast feeding only; indirect bilirubin level between 15-20 mg/dl on arrival; jaundice beginning at days 3-11 after birth; hematocrit level less than 65% or Hb under 20 Exclusion criteria: physical anomalies; previous remedy consumption; previous history of

jaundice therapy; sepsis

Age

To **1 year** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord University of Medical Science

Street address

Office of Medical Science, kashani street

City

Shahrekord

Postal code

8813833435

Approval date

2008-06-22, 1387/04/02

Ethics committee reference number

2-4-87

Health conditions studied

1

Description of health condition studied

Icteric non-hemolytic newborns

ICD-10 code

p59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Serum bilirubin level

Timepoint

On arrival and 12, 24, 48 and 72 hours after

Method of measurement

mg/dl

Secondary outcomes

1

Description

Duration of hospitalization

Timepoint

Day

Method of measurement

Days being hospitalized

Intervention groups

1

Description

Group1: prescribed 100 mg /kg clofibrate orally as single dose on arrival, in addition to phototherapy for 3 days.

Category

Treatment - Drugs

2

Description

Group 2: prescribed 5 mg /kg phenobarbital orally as single dose on arrival, in addition to phototherapy for 3 days.

Category

Treatment - Drugs

3

Description

Group 3: only resealed distilled water in addition to phototherapy for 3 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahrekord Hajar Hospital

Full name of responsible person

Dr. Hamidi

Street address

Hajar hospital, Varzesh Street, Shahrekord, IRAN

City

Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Science

Full name of responsible person

Vice Chancellery for Research, Dr. M Mobasheri

Street address

Vice Chancellery for Research, Shahrekord University of Medical Science, Kashani street, Shahrekord ,Iran

City

Shahrekord

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahrekord University of Medical Science

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**

Shahrekord University of Medical Science

Full name of responsible person

Dr. Majid Hamidi

Position

Academic member

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Person responsible for scientific inquiries

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Position

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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