

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of Phenobarbital in various doses on the duration of hospitalization in non-hemolytic neonatal jaundice under phototherapy

Protocol summary

Summary

Objectives: To determine the effect of different doses of phenobarbital on total serum bilirubin and duration of hospitalization of neonate with indirect hyperbilirubinemia treated with phototherapy. Design: Randomized controlled clinical trial Setting and conduct: The term neonate with indirect hyperbilirubinemia and indication for phototherapy were randomized into three groups and treated with different doses of phenobarbital. Duration of hospitalization and total serum bilirubin levels was measured at the beginning, 24 and 48 hours after the initiation of treatment. Participants including major eligibility criteria: Inclusion criteria: Term neonate; Weight $\geq$ 2500 g; Indirect hyperbilirubinemia; Indication for phototherapy Exclusion criteria: Hemolysis from any cause; Blood transfusions; Any previous traditional drug therapy or phototherapy Sample size: 90 term neonate Intervention: Group I- 10 mg/kg loading dose of phenobarbital on first day followed by 5 mg/kg/day till discharge plus phototherapy (n=30); Group II- 3.5 mg/day phenobarbital from day 1 till discharge plus phototherapy (n=30); Group III- Phototherapy. Main outcome measures (variables): Total serum bilirubin levels; Duration of hospitalization

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052628090N1**
Registration date: **2016-08-06, 1395/05/16**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-08-06, 1395/05/16

Registrant information

Name

Nafiseh Ataie

Name of organization / entity

Qazvin University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 28 3332 8709

Email address

n.ataie@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Science

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Phenobarbital in various doses on the duration of hospitalization in non-hemolytic neonatal jaundice under phototherapy

Public title

The effect of Phenobarbital on the duration of hospitalization in non-hemolytic neonatal jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Term neonate (> 37 weeks); Weight $\geq$ 2500 g; Indirect hyperbilirubinemia (Total bilirubin level: 17-20 mg/dL); Indication for phototherapy

Exclusion criteria: Hemolysis from any cause; Metabolic and endocrine disorders; Genetic or chromosomal disorders; Sepsis; Blood transfusions; Any previous traditional drug therapy or phototherapy ; Vitamin K deficiency or bleeding in newborns; History of taking vitamin K by the mother during pregnancy; Discharge of infants with personal consent of parents before completion of treatment; Lack of parental consent for treatment or study

Age

From **3 days** old to **5 days** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Qazvin university of Medical Science

Street address

Qazvin University Of Medical Sciences, Shahid Bahonar Blvd., Deputy for Research and Technology

City

Qazvin

Postal code

Approval date

2015-09-30, 1394/07/08

Ethics committee reference number

IR.QUMS.REC.1394.140

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Total serum bilirubin levels

Timepoint

before, 24 and 48 hours after the initiation of treatment

Method of measurement

Blood test

2

Description

Duration of hospitalization

Timepoint

Discharge time

Method of measurement

Patient file

Secondary outcomes

empty

Intervention groups

1

Description

Case group I: In addition to phototherapy, 10 mg/kg loading dose of phenobarbital was prescribed on first day followed by 5 mg/kg/day until the treatment of jaundice plus phototherapy.

Category

Treatment - Drugs

2

Description

Case group II: In addition to phototherapy, 3.5 mg/day phenobarbital was prescribed from day 1 until the treatment of jaundice plus phototherapy.

Category

Treatment - Drugs

3

Description

Control Group: Until the treatment of jaundice, just received phototherapy.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Qods hospital
Full name of responsible person
Nafiseh Ataei
Street address
Qods Hospital, East Palestine St.
City
Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Science
Full name of responsible person
Taghi Naserpour, Vice chancellor for research, Qazvin University of Medical Sciences
Street address
Qazvin University Of Medical Sciences, Shahid Bahonar Blvd., Deputy for Research and Technology, Qazvin, Iran
City
Qazvin

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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
Qazvin University of Medical Science
Full name of responsible person
Nafiseh Ataie
Position
Pediatric residents
Other areas of specialty/work
Street address
Qods Hospital, East Palestine St.
City
Qazvin
Postal code
Phone
+98 28 3333 4807
Fax

Email
dr.nafiseh.ataie@gmail.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical science
Full name of responsible person
Manoochehr Mahram
Position
Pediatricians
Other areas of specialty/work
Street address
Qods hospital, East Palestine St.
City
Qazvin
Postal code
Phone
+98 28 3333 4807
Fax
Email
drmahram@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Science
Full name of responsible person
Nafiseh Ataie
Position
Pediatric residents
Other areas of specialty/work
Street address
Qods Hospital, East Palestine St.
City
Qazvin
Postal code
Phone
+98 283333480700
Fax
Email
dr.nafiseh.ataie@gmail.com
Web page address

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