Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of single dose Phenobarbital on treatment of term and near term newborn'shyper bilirubinemia admitted in the hospital

Protocol summary

Summary

Term and near-term Babies (> 35 week) or (> 2500 g) with serum bilirubin levels in the therapeutic range (> 15 mg / dl) who admitted in bentolhoda hospital, Bojnord,Iran without signs of hemolysis, internal bleeding, G6PD sepsis, severe respiratory illness requiring mechanical ventilation and congenital anomalies are enrolled after parental consent. Since the Babies are eligible to enter the total number of samples is 60. Methods: in this case- control trial all babies enrolled in the study after routine tests, including blood group of baby and mother, G6PD, bil (t, d), coombs, Pbs, Hb, Hct, Retic were collected. Phenobarbital with dose (12 mg / kg) administered orally in one dose, randomly to half of babies in addition with phototherapy. Serum bil (T, D) after 24 and 72 hours was evaluated within all babies. Indication of starting and discontinuing phototherapy was planned as AAP guidelines (starting at bil>15mg/dl, discontinuing at 50-70% of bil T). Phototherapy duration also will be compared between case and control groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102919716N4**
Registration date: **2015-03-15, 1393/12/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-03-15, 1393/12/24

Registrant information

Name

Ghasem Bayani

Name of organization / entity

North Khorasan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

North Khorasan University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of single dose Phenobarbital on treatment of term and near term newborn'shyper bilirubinemia admitted in the hospital

Public title

Effect of single dose Phenobarbital on treatment of term and near term newborn'shyper bilirubinemia admitted in the hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Term and near-term babies (> 35 week) or (> 2500 g) with serum bilirubin levels in the therapeutic range (> 15 mg / dl) who admitted in hospital without signs of hemolysis, internal bleeding, G6PD, sepsis, severe respiratory illness requiring mechanical ventilation and

congenital anomalies are enrolled after parental consent.

Age

From **1 day** old to **7 days** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

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

North Khorasan University of Medical Sciences

Street address

North Khorasan University of Medical Sciences, Berenji alley, Bojnord, North Khorasan

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Bojnord

Postal code

2247124

Approval date

2014-10-18, 1393/07/26

Ethics committee reference number

756-93-پ

Health conditions studied

1

Description of health condition studied

Near term newborn's hyper bilirubinemia

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Serum bilirubin

Timepoint

Weeks 35-42

Method of measurement

Blood sample test

2

Description

Hematocrit,coombs,blood group,retic count

Timepoint

at birth time and starting treatment to discharge at hospital

Method of measurement

serum examination

Secondary outcomes

1

Description

Hospitalization period, phototherapy duration

Timepoint

Days of hospitalization, hours of phototherapy

Method of measurement

Medical records

Intervention groups

1

Description

In the intervention group babies receive phenobarbital with phototherapy. Phenobarbital with dose (12 mg / kg) administered orally in one dose. Indication of starting and discontinuing phototherapy was planned as AAP guidelines (starting at bil>15mg/dl, discontinuing at 50-70% of bil T).

Category

Treatment - Drugs

2

Description

Control group give only phototherapy,without phenobarbital

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Bentolhoda

Full name of responsible person

Ghasem Bayani

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Zayeshgah st., Bojnord, North Khorasan
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Sponsors / Funding sources

1

Sponsor
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Grant name
1 درصد
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
North Khorasan University of Medical Sciences
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

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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