

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Phenobarbital to Reduce Newborn Readmissions for Hyperbilirubinemia

Protocol summary

Study aim

Effect of Phenobarbital to Reduce Newborn Readmissions for Hyperbilirubinemia

Design

Randomised, parallel group trial of 142 patients, and followed for one week

Settings and conduct

Study will conduct on neonates of Izadi Qom Hospital on neonates admitted for jaundice during the first 10 days of birth

Participants/Inclusion and exclusion criteria

Inclusion criteria: Have a major risk factors for development of severe hyperbilirubinemia and hospitalized because of hyperbilirubinemia in the first 10 days of birth. Exclusion criteria: Major congenital malformations, Gestational age <35 weeks and Weight <2500 g at birth.

Intervention groups

Intervention group: Phenobarbital, oral, 3.5 mg/kg/day, for the first 7 days after discharge; Control group: No intervention

Main outcome variables

Rate of readmissions for neonatal jaundice within 7 days after discharge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170215032587N2**

Registration date: **2018-02-27, 1396/12/08**

Registration timing: **retrospective**

Last update: **2018-02-27, 1396/12/08**

Update count: **0**

Registration date

2018-02-27, 1396/12/08

Registrant information

Name

Mohammad Aghaali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 751 5639

Email address

maghaali@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-09, 1396/07/17

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

2017-10-09, 1396/07/17

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

empty

Scientific title

Effect of Phenobarbital to Reduce Newborn Readmissions for Hyperbilirubinemia

Public title

Effect of Phenobarbital Neonatal Icther

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Have a major risk factors for development of severe hyperbilirubinemia Hospitalized because of hyperbilirubinemia in the first 10 days of birth

Exclusion criteria:

Major congenital malformations Gestational age <35 weeks Weight <2500 g at birth History of blood

transfusion History of IVIG administration History of maternal use of phenobarbital in the last month of pregnancy Whose parents refused to give consent

Age

From **1 day** old to **10 days** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **142**

Actual sample size reached: **142**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization at the level of the individual

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 Qom University of Medical Sciences

Street address

No. 83, Alley 4, Alley 1.1, Safashahr Street, Qom

City

Qom

Province

Ghous

Postal code

3716987366

Approval date

2015-03-08, 1393/12/17

Ethics committee reference number

MUQ.REC.1393.138

2

Ethics committee

Approval date

empty

Ethics committee reference number

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

Rate of readmissions for neonatal jaundice

Timepoint

7 days after discharge

Method of measurement

Physician examination

Secondary outcomes

1

Description

Mean serum bilirubin levels

Timepoint

Before intervention and 1, 3, 5, 7 day after intervention

Method of measurement

Blood test

2

Description

Adverse effects of phenobarbital (feed intolerance, lethargy, apnea and cyanotic spells)

Timepoint

During 1 weeks after intervention

Method of measurement

Physician examination

Intervention groups

1

Description

Intervention group: Phenobarbital, oral, 3.5 mg/kg/day, for the first 7 days after discharge

Category

Treatment - Drugs

2

Description

Control group: no intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Izadi hospital

Full name of responsible person

Parvaneh Sadeghi-moghaddam

Street address

Izadi hospital, Azar Ave, Qom

City

Qom

Province

Ghoum

Postal code

3715888566

Phone

+98 25 3721 1301

Email

Psadeghi@muq.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Hossein Saghafi

Street address

No. 83, Alley 4, Alley 1.1, Safashahr Street, Qom

City

Qom

Province

Ghoum

Postal code

3716987366

Phone

+98 25 3285 2720

Email

hsaghafi@muq.ac.ir

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

Yes

Title of funding source

Ghoum 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

Ghoum University of Medical Sciences

Full name of responsible person

Mohammad Aghaali

Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work

Epidemiology

Street address

Qom University of Medical Science, Saheli Street, Qom

City

Qom

Province

Ghoum

Postal code

3713649373

Phone

+98 25 3285 2720

Fax

+98 25 3285 8464

Email

maghaali@muq.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ghoum University of Medical Sciences

Full name of responsible person

Mohammad Aghaali

Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work

Epidemiology

Street address

Qom University of Medical Science, Saheli Street, Qom

City

Qom

Province

Ghoum

Postal code

3713649373

Phone

+98 25 3285 2720

Fax

+98 25 3285 8464

Email

maghaali@muq.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Mohammad Aghaali

Position

Medical Doctor

Latest degree

Medical doctor

Other areas of specialty/work

Epidemiology

Street address

Qom University of Medical Science, Saheli Street,

Qom

City

Qom

Province

Ghous

Postal code

3713649373

Phone

+98 25 3285 2720

Fax

+98 25 3285 8464

Email

maghaali@muq.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The data are specific to this study

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available