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 Ichter
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
Ghoum

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
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

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