Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Evaluation of clofibrate effect in hyperbilirubinemia of healthy term neonates

Protocol summary

Summary

The purpose of this study was to evaluate effectiveness and side effects of single dose of 50 mg/kg clofibrate in the treatment of hyperbilirubinemia of term healthy neonates. A randomized clinical trial was conducted on 60 healthy term neonates with hyperbilirubinemia and bilirubin level of 17-29.9 mg/dL admitted to Yazd Shaheed Sadoughi Hospital. The patients were randomly assigned to receive phototherapy alone or single dose of 50 mg/kg clofibrate as well as phototherapy. Total serum bilirubin levels were measured at the beginning, 12, 24, and 48 hours after the start of phototherapy and until total serum bilirubin (TSB) declined to less than 14 mg/dl. All neonates were evaluated during hospital stay and on the second day after discharge in terms of side-effects of treatment. At the end of the treatment, total serum bilirubin, hospital stay, time of treatment with phototherapy, and side effects were compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008172639N3**
Registration date: **2010-09-13, 1389/06/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-09-13, 1389/06/22

Registrant information

Name

Razieh Fallah

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Country

Iran (Islamic Republic of)

Phone

+98 35 3822 4000

Email address

fallah@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shaheed Sadoughi Medical Sciences and Health Services University

Expected recruitment start date

2007-06-22, 1386/04/01

Expected recruitment end date

2007-12-21, 1386/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clofibrate effect in hyperbilirubinemia of healthy term neonates

Public title

Clofibrate in icter

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Gestation age of 38-42 weeks, Birth weight of 2500-4000 grams, Product of normal vaginal delivery, Bilirubin level of 17-29.9 mg/dL Exclusion criteria: Neonates with sepsis, anemia and hemolytic diseases, indirect hyperbilirubinemia, underlying hepatic disorders

Age

To **1 year** old

Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shaheed Sadoughi University of Medical Sciences
Street address
Shaheed Bahonar square
City
Yazd
Postal code
Approval date
2007-05-31, 1386/03/10
Ethics committee reference number
40346/1/17/پ

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 level
Timepoint
12, 24, and 48 hours after beginning of the treatment
Method of measurement
laboratory analysis

Secondary outcomes

1

Description
hospital stay
Timepoint
in days
Method of measurement
counting of stay days based on medical records

2

Description
Time of treatment with phototherapy
Timepoint
At the end of the treatment
Method of measurement
review of medical record

3

Description
Side effects
Timepoint
during hospital stay and on the second day after discharge
Method of measurement
clinical evaluation

Intervention groups

1

Description
Phototherapy alone
Category
Treatment - Other

2

Description
Single dose of 50 mg/kg clofibrate as well as phototherapy
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
NICU, Shaheed Sadoughi Hospital
Full name of responsible person
Saeid Reza Lotfi MD
Street address
Shaheed Ghandi Blvd, Ave sina St, Safaeeih
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shaheed Sadoughi University of Medical Sciences and Health Services
Full name of responsible person
Fatemah Ezoddini, MD
Street address
Bahonar Square
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shaheed Sadoughi University of Medical Sciences and Health Services
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shaheed Sadoughi University of Medical Sciences and Health Services
Full name of responsible person
Zia Islami
Position
Associate professor
Other areas of specialty/work
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Email
Kavosh252006@yahoo.com
Web page address

Person responsible for updating data

Contact

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