Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Evaluating the effect of low dose vs moderate dose clofibrate on decreasing serum bilirubin in healthy full term neonates

Protocol summary

Summary

This randomized clinical trial study was performed to assess effect of different dose of clofibrate on neonatal jaundice.The inclusion criteria included: age of 2 to 29 days; full term newborn (gestational age between 38 to 40 weeks); weight of 2500 to 4000 gr; having indirect hyperbilirubinemia (TSB>16mg/dl); absence of hemolysis, ABO or Rh incompatibility; negative coomb's test; reticulocyte count less than 5%. We enrolled 132 neonates with non-hemolytic indirect hyperbilirubinemia admitted in the neonatal ward of Beasat hospital in Hamadan city, during a nine-month period. The patients were randomly assign to three groups : control group receiving only phototherapy; intervention group 1 receiving a single low dose of oral clofibrate (25 mg/kg) plus phototherapy; intervention group 2 receiving a single moderate dose of oral clofibrate (50 mg/kg) plus phototherapy. Total and indirect bilirubin level was measured in all groups at baseline and 12, 24, 36 and 48 hours after treatment. All neonates were visited in outpatient clinic two days after discharge. No adverse effects were seen subsequent to clofibrate administration.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012092910933N1**
Registration date: **2012-10-25, 1391/08/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-10-25, 1391/08/04

Registrant information

Name

Fatemeh Eghbalian

Name of organization / entity

Hamadan University of Medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Hamadan University Of Medical Sciences

Expected recruitment start date

2008-09-22, 1387/07/01

Expected recruitment end date

2009-06-20, 1388/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of low dose vs moderate dose clofibrate on decreasing serum bilirubin in healthy full term neonates

Public title

Evaluating the effect of low dose vs moderate dose clofibrate on decreasing serum bilirubin in healthy full term neonates

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: (a) age of 2 to 29 days; (b) full term newborn (gestational age between 38 to 40 weeks); (c) weight of 2500 to 4000 gr; having indirect

hyperbilirubinemia (TSB>16 mg/dl) ; (d) absence of hemolysis, ABO or Rh incompatibility; (e) negative coomb’s test; (f) reticulocyte count less than 5%. Exclusion criteria : The neonates with sign of sepsis, electrolyte impairment, any congenital anomalies or disease, seizure, formula feeding, hemolytic disease and those who need exchange transfusion were excluded from the study.

Age
From **1 year** old to **1 year** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **132**

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
Hamadan University of Medical Sciences

Street address
Mahdie Ave, Hamadan university of Medical sciences, Hamedan, Iran

City
Hamedan

Postal code
6514845411

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
16/35/9/116602/پ

Health conditions studied

1

Description of health condition studied
Neonatal jaundice

ICD-10 code
P59.9

ICD-10 code description
P59.9 Neonatal jaundice, unspecified

Primary outcomes

1

Description
Bilirubin

Timepoint
Total and indirect bilirubin levels were measured at the beginning of treatment and then 12, 24, 36 and 48 hours later

Method of measurement
RA1000 Techinca

Secondary outcomes

1

Description
Bilirubin

Timepoint
Total and indirect bilirubin levels were measured at the beginning of treatment and then 12, 24, 36 and 48 hours later

Method of measurement
RA1000 Techinca

Intervention groups

1

Description
control group receiving only phototherapy

Category
Treatment - Drugs

2

Description
intervention group 1 receiving a single low dose of oral clofibrate (25 mg/kg) plus phototherapy

Category
Treatment - Drugs

3

Description
intervention group 2 receiving a single moderate dose of oral clofibrate (50 mg/kg) plus phototherapy.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Bessat Hospital - Neonatal Ward

Full name of responsible person
Dr Fatemeh Eghbalian
Street address
Motahari Ave, Bessat Hospital, Hamedan, Iran
City
Hamedan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamadan University of Medical Sciences
Full name of responsible person
Dr Hydar Tavilani
Street address
Mahdie Ave, Hamadan University of Medical Sciences,Hamadan,Iran
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamadan 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

Person responsible for general inquiries

Contact
Name of organization / entity
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Other areas of specialty/work
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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