Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Clofibrate in Jaundiced term Newborns

Protocol summary

Summary

The aim of this study was to determine the therapeutic effect of clofibrate in healthy term jaundiced neonates. Healthy, breastfed neonates,uncomplicated delivery between 38 th and 41 st weeks gestational age were included and babies with congenital anomaly, hemolytic disease (Rh or ABO incompatibility and a positive coombs' test), infection (congenital or acquried), dehydration, G6PD deficiency and conjugated bilirubin>2.0 mg/dl or exceeding 15% of total serum bilirubin were excluded. Thirty neonates (treatment group) were treated with a single oral dose of clofibrate (100 mg/kg) plus phototherapy while another 30 neonates (control group) received only phototherapy. The mean plasma total bilirubin levels were measured at 12, 24 and 48 hours after treatment. Duration of phototherapy also was recorded. Phyisical examination and liver function tests were controlled for possible side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706261162N4**
Registration date: **2008-10-28, 1387/08/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2008-10-28, 1387/08/07

Registrant information

Name

Ashraf Mohammadzadeh

Name of organization / entity

Neonatal Research Center of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1852 1121

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2002-11-02, 1381/08/11

Expected recruitment end date

2003-07-09, 1382/04/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Clofibrate in Jaundiced term Newborns

Public title

Effect of Clofibrate in Jaundiced Term newborns

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: healthy jaundiced, breastfed neonates, delivered between 38th and 41st week of gestational age after an uncomplicated pregnancy and serum bilirubin(TSB) between 17 and 29.9 mg/dl ,age less than 28 days exclusion criteria: congenital anomaly, hemolytic disease (Rh or ABO incompatibility and a positive coombs' test), infection (congenital or acquired), dehydration, G6PD deficiency and conjugated bilirubin>2.0 mg/dl or exceeding 15% of total serum bilirubin,age more than 28 days

Age

From **3 years** old to **19 years** old

Gender

Both

Phase
3
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

1

Registry name
Secondary trial Id
Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-chancellor of Mashhad University of Medical Sciences
Street address
Ghoreshi bulding-Daneshgah Street-Mashhad-Iran
City
Mashhad
Postal code
91379-13131
Approval date
2002-12-02, 1381/09/11
Ethics committee reference number
15169/824

Health conditions studied

1

Description of health condition studied
Jaundice in healthy, term newborn
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Serum bilirubine
Timepoint
Before intervention-12,24 and 48 after intervention
Method of measurement
Measuring serum bilirobin(diazo method)

Secondary outcomes

1

Description
Duration of need to phototrapy
Timepoint
daily
Method of measurement
Duration of phototherapy (days)

Intervention groups

1

Description
Phototherapy + clofibrate(100 mg/kg, single dose)
Category
empty

2

Description
Phototherapy
Category
empty

Recruitment centers

1

Recruitment center
Name of recruitment center
NICU Emaereza hospital-Neonatal Research Center
Full name of responsible person
Ashraf Mohammadzadeh
Street address
Neonatal research center- NICU- Emamreza hospital-mashhad-Iran
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Street address
City
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Neonatal Research Center
Full name of responsible person
Ashraf mohammadzadeh
Position
Neonatologist, Professor
Other areas of specialty/work
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Person responsible for updating data

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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