Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of clofibrate in low birth weight neonates' hyperbilirubinemia

Protocol summary

Summary

The goal of this study was to evaluate the effect of Clofibrate in the treatment of jaundice in low birth weight newborns. In a randomized double blind placebo – controlled study, low birth weight infants with the complaint of icter are selected. Study participants receive either clofibrate 100 mg/kg or distilled water once time/ day. Then they receive phototherapy and their bilirubin level is measured in 12hr, 24hr, 48hr, and 72 hr afterword.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138708291162N8**
Registration date: **2009-01-20, 1387/11/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-01-20, 1387/11/01

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

Email address

mohamadzadeha@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

mashhad university of medical science

Expected recruitment start date

2006-09-30, 1385/07/08

Expected recruitment end date

2007-04-27, 1386/02/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of clofibrate in low birth weight neonates' hyperbilirubinemia

Public title

Effect of clofibrate in low birth weight neonates' hyperbilirubinemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:All neonates with birth weight less than 2500gr who have icter. Exclusion criteria: the presence of a hemolytic, infection, congenital anomaly or metabolic disorder and undergoing mechanical ventilation.

Age

From **2 years** old to **28 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

vice chanceler of mashad university of medical scienc

Street address

ghoreshi bilding-daneshgah street

City

mashhad

Postal code

91379-13131

Approval date

empty

Ethics committee reference number

12502/824

Health conditions studied

1

Description of health condition studied

low birth weight

ICD-10 code

P07.1

ICD-10 code description

Other low birth weight

2

Description of health condition studied

hyperbilirubinemia

ICD-10 code

P59.0

ICD-10 code description

Neonatal jaundice associated with preterm delivery

Primary outcomes

1

Description

decreasing of serum bilirubin

Timepoint

befor intervention and 12,24,48,72 and 96 hours after intervention

Method of measurement

measurment of serum bilirubin (diazo method)

Secondary outcomes

1

Description

tereatment of jaundice of neonate

Timepoint

befor intervention and 24,48,72 and 96 hours after intervention

Method of measurement

decreasing of jaundice and bilirubin level in blood serum

Intervention groups

1

Description

in cases: clofibrate 100 mg/kg once time/ day

Category

Treatment - Drugs

2

Description

in controls: distilled water once time/ day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU Emaereza hospital-Neonatal Research Center

Full name of responsible person

dr.Ashraf mohammadzadeh

Street address

Neonatal research center- NICU- Emamreza hospital

City

mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

mashhad university of medical science

Full name of responsible person

Dr jalil tavakol afshari

Street address

ghoreshi bulding-daneshgah street-mashhad-Iran

City

mashhad

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 science

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
Neonatal Research Center

Full name of responsible person
Dr.Ashraf mohammadzadeh

Position
Neonatologist, professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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