

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Prophylactic effect of colofibrate in very low birth weight neonates' hyperbilirubinemia

Protocol summary

Summary

The aim of this study was to determine the prophylactic effect of colofibrate in very low birth weight (birth weight < 2500 gm) neonate's hyperbilirubinemia. In a randomized double blind clinical trial 52 very low birth weight neonates were elected. Healthy very low birth weight neonates who were admitted in NICU were included and neonates with hemolysis, infection, congenital anomalies and metabolic diseases were excluded. Study participants received either single dose of colofibrate 100 mg/kg (n=26) or sterile water as volume as colofibrate (n=26) by Orogastric tube. Serum bilirubin levels were measured at entrance, 24, 48, 72 and 96 hours after intervention. Duration of phototherapy also was recorded in two groups. Physical exam and liver function tests for drug side effects were controlled.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706311162N5**

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

Email address

mohamadzadeha@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2006-04-06, 1385/01/17

Expected recruitment end date

2007-01-07, 1385/10/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic effect of colofibrate in very low birth weight neonates' hyperbilirubinemia

Public title

Prophylactic effect of colofibrate in very low birth weight neonates' hyperbilirubinemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion: low birth weight neonates who were admitted to NICU of Emamreza Hospital. These neonates were healthy, breastfed with birth weight equal or less than 2500 grams. exclusion: Babies with hemolysis, infections, congenital anomalies and metabolic diseases were excluded

Age

From **1 year** old to **10 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

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 bilding-Daneshgah street-Mashhad-Iran

City

Mashhad

Postal code

9137913316

Approval date

2006-04-19, 1385/01/30

Ethics committee reference number

5/6833

Health conditions studied

1

Description of health condition studied

Hyperbilirubinemia in low birth weight neonates

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum Bilirubin

Timepoint

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

Method of measurement

measurment of serum bilirubin (diazot method)

Secondary outcomes

1

Description

Incidence of jaundice in low birth weight neonates

Timepoint

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

Method of measurement

Physical examination (yes/no)

Intervention groups

1

Description

100 mg/kilogram clofibrate

Category

empty

2

Description

The same volume of strile water as Placebo

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

Street address

NRC-NICU-Emaereza hospital-mashhad-Iran

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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