

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Prophylactic effect of clofibrate on prevention of jaundice in very low birth weight twin pregnancy neonates

Protocol summary

Summary

The aim of this study was to determine the prophylactic effect of clofibrate in twin pregnancy very low birth weight (birth weight < 1500 gm) neonates hyperbilirubinemia. In a randomized double blind clinical trial 50 very low birth weight neonates who are twin pregnancy with single sex(male) entered to study. Healthy very low birth weight neonates who are admitted to NICU and are twin pregnancy with similar gender as including and neonates with hemolysis, excessive external bleeding, G6PD, sepsis, infection, severe respiratory disease need to ventilation, congenital anomalies and metabolic diseases are excluded. Study participants receive either single dose clofibrate 100 mg/kg (clofibrat group n=25) or sterile water as volume as clofibrate (control group n=25) by orogastric tube. Serum bilirubin levels are measured at entrance, 24, 48, 72 and 96 hours of study. Duration of phototherapy also is recorded in two groups. Physical exam and liver function tests for drug side effects are controlled

Neonatal Research Center of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Mashhad university of medical sciences

Expected recruitment start date

2010-09-25, 1389/07/03

Expected recruitment end date

2011-08-25, 1390/06/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811061162N15**

Registration date: **2011-01-26, 1389/11/06**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-01-26, 1389/11/06

Registrant information

Name

Ashraf Mohammadzadeh

Name of organization / entity

Scientific title

Prophylactic effect of clofibrate on prevention of jaundice in very low birth weight twin pregnancy neonates

Public title

Prophylactic effect of clofibrate on prevention of jaundice in very low birth weight twin pregnancy neonates

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: twin pregnancy with same gender very low birth weight neonates who are admitted to NICU of Emamreza Hospital. These neonates are healthy, with birth weight equal or less than 1500 grams. Exclusion criteria: Babies with hemolysis, excessive external bleeding, G6PD, sepsis, infection, severe respiratory disease need to ventilation, congenital anomalies and

metabolic diseases are excluded

Age

From **1 year** old to **2 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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 chancellor for research of Mashhad University of medical sciences

Street address

Ghoreshi building, Daneshgah street

City

Mashhad

Postal code

13131-91379

Approval date

2010-09-25, 1389/07/03

Ethics committee reference number

1978/511

Health conditions studied**1****Description of health condition studied**

Very low birth weight hyperbilirubinemia

ICD-10 code

P07.1

ICD-10 code description

Other low birth weight

Primary outcomes**1****Description**

serum bilirubin

Timepoint

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

Method of measurement

measurement of serum bilirubin (diazotization method)

Secondary outcomes**1****Description**

jaundice

Timepoint

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

Method of measurement

observation

Intervention groups**1****Description**

Intervention group: 100 mg of clofibrate

Category

Prevention

2**Description**

Control group: sterile water

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Neonatal Research Center & NICU of Emaareza hospital

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 sciences

Full name of responsible person

Dr. Jalil Tavakol Afshari

Street address
Ghoreshi bulding, Daneshgah street
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 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
Neonatal Research Center
Full name of responsible person
Dr. Ashraf Mohammadzadeh
Position
Neonatologist, professor
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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