

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of Clofibrate on the prevention of jaundice in healthy term neonate group)

Protocol summary

Summary

The aim of this study is evaluation the effect of Clofibrate on the prevention of jaundice in term neonates. All term neonate (37 - 41 week of Gestational Age, 6/7) who are otherwise health and resulting from a non-complicated pregnancy, will be enrolled in the study. Exclusion criteria include: Term infants with overt jaundice in the first day after birth; Direct hyperbilirubinemia more than 1 mg/dl; Sick neonates; Infants born to mothers under phenobarbital treatment; Low birth weight neonate (birth weight less than 2500 gr); Preterm neonate (the gestational age less than 37 weeks) and neonates with Rh incompatibility; In this clinical trial neonates will be put into two groups; 40 neonates will receive one dose of oral Clofibrate (50 mgr per kgr) within first hour after birth and after first breast feed. Other 40 neonates won't take any medication and defined as control group. Both groups then will be followed closely for jaundice. The bilirubin level of two gropes will be measured by Bilirubinometers in 24, 48, and 72 hours after birth. The plasma level of bilirubin will be checked when the skin bilirubin are more than 10 mgr/dl. The primary level of total and direct bilirubin, blood group, RH, and G6PD level will be measured in umbilical cord blood sample. The mother's blood group will be recorded using patient's medical document review.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013031312803N1**

Registration date: **2013-05-28, 1392/03/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-28, 1392/03/07

Registrant information

Name

Sadroddin Mahdipour

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1324 6963

Email address

smb1355@gmail.com

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences is sponsoring the project.

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Clofibrate on the prevention of jaundice in healthy term neonate group)

Public title

Effect of clofibrate on the prevention of jaundice in term neonate

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria :All term neonate (37 - 41 week of

Gestational Age, 6/7) who are otherwise health and resulting from a non-complicated pregnancy Exclusion criteria include: Term infants with overt jaundice in the first day after birth; Direct hyperbilirubinemia more than 1 mg/dl; Sick neonates; Infants born from mothers under phenobarbital treatment; Low birth weight neonate (birth weight less than 2500 gr); Preterm neonate (the gestational age less than 37 weeks) and neonates with Rh incompatibility.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

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**

Babol University Of Medical Sciences

Street address

Babol University Of Medical Sciences, Ganjafroz street

City

Babol

Postal code**Approval date**

2013-01-22, 1391/11/03

Ethics committee reference number

2006/30/پ/ز

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

neonatal jaundice

ICD-10 code

P59.9

ICD-10 code description

Physiological jaundice (intense)(prolonged) NOS

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

Total Bilirubin

Timepoint

Umbilical cord and 24,48,72 hours after birth

Method of measurement

with Bilirubinometer

Secondary outcomes

empty

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

Prescription of Clofibrate(50 mg per kg of body weight ,orally) during the first hour after birth and after fist meal of breastfeeding in the intervention group

Category

Treatment - Drugs

2**Description**

there is no intervention in the control group

Category

Other

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

Aiatollah Rohani Hospital

Full name of responsible person

Mrs Mariam Taheri

Street address

Nursery Ward, Aiatollah Rohani Hospital, Ganjafroz Street

City

Babol

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Babol University of Medical Sciences ,

Full name of responsible person

Dr Amrollah Mostafazadeh

Street address

Babol University of Medical Sciences

City
Babol

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Dr Sadroddin Mehdipour

Position
Neonatal Fellowship

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Babol univesity

Full name of responsible person
Dr Yadollah Zahad Pasha

Position

Neonatologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Dr Sadroddin Mehdipour

Position
Neonatal Fellowship

Other areas of specialty/work

Street address
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+98 11 1325 2988

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Email
smb1355@gmail.com

Web page address

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