Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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/ژ/پ

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
Umbillical cord and 24,48,72 hours after birhbirth bilirubin

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
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Full name of responsible person
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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