Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

Comparing the effect of phototherapy plus different doses of Clofibrate in level of bilirubin in term newborns with non- hemolytic Icter

Protocol summary

Study aim
Comparing the effect of different doses of Clofibrate plus phototherapy in level of bilirubin in term newborns with non- hemolytic Icter

Design
Double blind, parallel group randomized-controlled clinical trial with 90 cases are divided into 2 intervention groups each of them include 30 cases and one control group includes 30 cases.

Settings and conduct
In this double blind, randomized-controlled clinical trial , which is done to investigate the effect of Colofibrate on jaundice, 90 neonates with jaundice in Taleghani hospital, Iran, according to the inclusion and exclusion criteria, are divided into three groups of thirty.After filling the permission form with parents, care giver divides the neonates according to the random numbers and random numbers generator software into three groups and parents are not aware of the type of intervention. Nurse provider prescribes a medicine or placebo placed in the same syringes of 0.5 cc and placed inside the envelope with the code assigned to each patient before starting phototherapy. Outcome assessor dose not know the intervention and data is entered into the questionnaire based on the patient code.The methodologist analysis given data based on specific code by using the data analysis software.

Participants/Inclusion and exclusion criteria
Inclusion criteria :Term neonates (gestational age more than 38 weeks) ; Asian race ; Iranian ; 2-14 day-old ; Non-hemolytic Jaundice ; Total serum bilirubin (TSB)=13-20 mg/dl Exclusion criteria: Hemolytic Jaundice ; TSB>20 mg/dl ; Sepsis

Intervention groups
First intervention group: A single dose of Clofibrate Capsule 50 mg/kg orally (Alhavi Company) before phototherapy. Second intervention group:A single dose of Clofibrate Capsule 100 mg/kg orally (Alhavi Company) before phototherapy. Control group:Placebo(sterile water, Alhavi Company) before phototherapy.

Main outcome variables
Total serum bilirubin (TSB)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180610040036N1**
Registration date: **2018-12-28, 1397/10/07**
Registration timing: **retrospective**

Last update: **2018-12-28, 1397/10/07**
Update count: **0**

Registration date
2018-12-28, 1397/10/07

Registrant information

Name
Narges Gholami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4442 7956

Email address
nargesgholami@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-05-22, 1396/03/01

Expected recruitment end date
2018-05-22, 1397/03/01

Actual recruitment start date
2017-07-23, 1396/05/01

Actual recruitment end date

2018-05-22, 1397/03/01

Trial completion date

2018-05-22, 1397/03/01

Scientific title

Comparing the effect of phototherapy plus different doses of Clofibrate in level of bilirubin in term newborns with non- hemolytic Icter

Public title

Effect of Clofibrate in term neonatal jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term neonates(gestational age more than 38 weeks) Iranian,Asian race 2-14 day-old Non-hemolytic icter Total serum bilirubin(TSB)=13-20 mg/dl

Exclusion criteria:

Hemolytic icter Total serum bilirubin(TSB) >20 mg/dl Sepsis

Age

From **2 days** old to **14 days** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

First, a framework was made of numbers 1-90 , then the assignment of these numbers to group 1-3 was determined based on the random numbers table. A computer software program (www.random.org) was used to produce random numbers to allocate the medication and placebo to 3 groups. Adequate medication and placebo for each group were be placed in a envelope marked with neonate number and medication code.

Blinding (investigator's opinion)

Double blinded

Blinding description

After filling the permission form with parents, care giver divides the neonates according to the random numbers and random numbers generator software into three groups and parents are not aware of the type of intervention. Nurse provider prescribes a medicine or placebo placed in the same syringes of 0.5 cc and placed inside the envelope with the code assigned to each patient before starting phototherapy. Outcome assessor dose not know the intervention and data is entered into the questionnaire based on the code of each person. Data analyser analysed final data based on specific code and software.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti university of medical sciences

Street address

Kodakyar st , Shahriary Sq , Chamran High way,

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2017-04-30, 1396/02/10

Ethics committee reference number

IR.SBMU.RETECH.REC.1396.77

Health conditions studied

1

Description of health condition studied

Neonatal jaundice

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

Total serum bilirubin level

Timepoint

Total serum bilirubin level before intervention then 6,12,24,48,72 hours after intervention

Method of measurement

Mindray BS-200 analyzer

Secondary outcomes

1

Description

Cholesterol

Timepoint
At bedtime before intervention , 72 hours after intervention
Method of measurement
Mindray BS-200 analyzer

2

Description
Triglycerides
Timepoint
At bedtime before intervention , 72 hours after intervention
Method of measurement
Mindray BS-200 analyzer

Intervention groups

1

Description
Intervention group 1: Clofibrate 50 mg/kg (Clofibrate of ALHAVI made in Iran , Oral single dose before phototherapy)
Category
Treatment - Drugs

2

Description
Intervention group 2: Clofibrate 50 mg/kg (Cofibrate of ALHAVI made in Iran , Oral single dose before phototherapy)
Category
Treatment - Drugs

3

Description
Control group: placebo (1 milliliter of sterile water vial, Oral single dose before phototherapy)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Ali Naseh
Street address
Taleghani hospital ,Yaman st , Velenjak
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1985711151
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taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak
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1985717434
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Narges Gholami
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Not applicable
Title and more details about the data/document
Final data has been given to Vice-Chancellor of Research Affairs of Shahid Beheshti University of Medical Sciences
When the data will become available and for how long
22 June 2018-20 March 2019
To whom data/document is available
pediatricians
Under which criteria data/document could be used
All researchers are allowed to receive data details and protocols according professional ethics
From where data/document is obtainable
Contact with authors
What processes are involved for a request to access data/document
By email to author(nargesgholami@sbmu.ac.ir). It takes about 7 days.
Comments