

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of clofibrate effect in hyperbilirubinemia of healthy term neonates

#### Protocol summary

##### Summary

The purpose of this study was to evaluate effectiveness and side effects of single dose of 50 mg/kg clofibrate in the treatment of hyperbilirubinemia of term healthy neonates. A randomized clinical trial was conducted on 60 healthy term neonates with hyperbilirubinemia and bilirubin level of 17-29.9 mg/dL admitted to Yazd Shaheed Sadoughi Hospital. The patients were randomly assigned to receive phototherapy alone or single dose of 50 mg/kg clofibrate as well as phototherapy. Total serum bilirubin levels were measured at the beginning, 12, 24, and 48 hours after the start of phototherapy and until total serum bilirubin (TSB) declined to less than 14 mg/dl. All neonates were evaluated during hospital stay and on the second day after discharge in terms of side-effects of treatment. At the end of the treatment, total serum bilirubin, hospital stay, time of treatment with phototherapy, and side effects were compared between groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201008172639N3**

Registration date: **2010-09-13, 1389/06/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-09-13, 1389/06/22

##### Registrant information

##### Name

Razieh Fallah

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd,

Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3822 4000

##### Email address

fallah@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shaheed Sadoughi Medical Sciences and Health Services University

##### Expected recruitment start date

2007-06-22, 1386/04/01

##### Expected recruitment end date

2007-12-21, 1386/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of clofibrate effect in hyperbilirubinemia of healthy term neonates

##### Public title

Clofibrate in icter

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Gestation age of 38-42 weeks, Birth weight of 2500-4000 grams, Product of normal vaginal delivery, Bilirubin level of 17-29.9 mg/dL Exclusion criteria: Neonates with sepsis, anemia and hemolytic diseases, indirect hyperbilirubinemia, underlying hepatic disorders

##### Age

To **1 year** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 60

**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**

Shaheed Sadoughi University of Medical Sciences

**Street address**

Shaheed Bahonar square

**City**

Yazd

**Postal code****Approval date**

2007-05-31, 1386/03/10

**Ethics committee reference number**

40346/1/17/پ

**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**

12, 24, and 48 hours after beginning of the treatment

**Method of measurement**

laboratory analysis

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

hospital stay

**Timepoint**

in days

**Method of measurement**

counting of stay days based on medical records

**2****Description**

Time of treatment with phototherapy

**Timepoint**

At the end of the treatment

**Method of measurement**

review of medical record

**3****Description**

Side effects

**Timepoint**

during hospital stay and on the second day after discharge

**Method of measurement**

clinical evaluation

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

Phototherapy alone

**Category**

Treatment - Other

**2****Description**

Single dose of 50 mg/kg clofibrate as well as phototherapy

**Category**

Treatment - Drugs

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

NICU, Shaheed Sadoughi Hospital

**Full name of responsible person**

Saeid Reza Lotfi MD

**Street address**

Shaheed Ghandi Blvd, Ave sina St, Safaeieh

**City**

Yazd

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shaheed Sadoughi University of Medical Sciences and Health Services

**Full name of responsible person**

Fatemah Ezoddini, MD

**Street address**

Bahonar Square

**City**

Yazd

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shaheed Sadoughi University of Medical Sciences and Health Services

**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**

Shaheed Sadoughi University of Medical Sciences and Health Services

**Full name of responsible person**

Zia Islami

**Position**

Associate professor

**Other areas of specialty/work**

**Street address**

Shaheed Sadoughi Hospital

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Yazd

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+98 35 1822 4000

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Kavosh252006@yahoo.com

**Web page address**

### 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*