

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison of efficacy of Billineaster drop and Glycerin suppository on the neonatal jaundice

#### Protocol summary

##### Summary

In a randomized clinical trial, 60 term (GA 35-37wks) newborns with 24-120 hours age; serum bilirubin level 14-20 mg/dl; birth weight 2500-4000 grams; exclusively breast fed; direct bilirubin <2mg/dl and without kernicterus symptoms; hemolysis; need for blood exchange; sepsis or history of any treatment for jaundice before hospitalization, randomly divided in 3 groups (20 newborns in each group). The first group receive billineaster 5drops/kg every 8hrs; the second group receive glycerin 1/2 suppository every 12hrs; and third group is control. For all three groups, phototherapy will be done with the same conditions. Total serum bilirubin level will be assayed 12, 24, 36 and 48 hours after initiation of treatment in all three groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013031312807N1**

Registration date: **2013-05-01, 1392/02/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-05-01, 1392/02/11

##### Registrant information

##### Name

Mohammad Ali Fallahzadeh

##### Name of organization / entity

Shaheed Sadoughi University of Medical Sciences and Health Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 1822 4000

##### Email address

drfallahzadeh@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Deputy of research -Shaheed Sadoughi University of Medical Sciences

##### Expected recruitment start date

2012-09-22, 1391/07/01

##### Expected recruitment end date

2013-03-20, 1391/12/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of efficacy of Billineaster drop and Glycerin suppository on the neonatal jaundice

##### Public title

Billineaster and glycerin in neonatal jaundice

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age 24-120 hrs; gestational age: term (37-42 weeks); birth weight: 2500-4000 grams; breast feeding exclusively; total serum bilirubin 14-20 mg/dl; no symptoms of kernicterus and not receiving any treatment (phototherapy, billineaster, glycerin,...) before hospitalization. Exclusion criteria: hemolysis or sepsis; need for blood exchange and weight loss >5%.

##### 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)

Double 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 and Health Services

##### Street address

Bahonar square

##### City

Yazd

##### Postal code

#### Approval date

2011-10-10, 1390/07/18

#### Ethics committee reference number

17/1/97215/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

Serum total bilirubin

#### Timepoint

Every 12 hours until 48 hours

#### Method of measurement

Labratory tast

## Secondary outcomes

### 1

#### Description

Fequency of deffication

#### Timepoint

Daily

#### Method of measurement

Clinical

### 2

#### Description

Weight

#### Timepoint

Daily

#### Method of measurement

With scale

### 3

#### Description

Duration of hospitalization

#### Timepoint

At discharge

#### Method of measurement

From admission to discharge

## Intervention groups

### 1

#### Description

Billineaster 5 drop/kg q8hr, until 48hrs.

#### Category

Treatment - Drugs

### 2

#### Description

Glycerin suppository 1/2 q12hrs until 48hrs.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Sadoughi hospital h- nicu

##### Full name of responsible person

Dr Mahmood Noori Shadkam

##### Street address

Yazd - Ibn sina ave

##### City

Yazd

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Deputy of research -Shaheed Sadoughi University of Medical Sciences

**Full name of responsible person**

Dr. Fatemah Ezodinee

**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**

Deputy of research -Shaheed Sadoughi 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**

Shaheed Sadoughi University of Medical Sciences and Health Services

**Full name of responsible person**

Mohammad Ali Fallahzadeh

**Position**

MD, resident of pediatric disease

**Other areas of specialty/work****Street address**

Shahid Bahonar sq.

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drfallahzadeh@ssu.ac.ir

**Web page address**

### Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shaheed Sadoughi University of Medical Sciences and Health Services

**Full name of responsible person**

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**Position**

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### Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

Mohammad Ali Fallahzadeh

**Position**

MD, resident of pediatric disease

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Shahid Bahonar sq.

**City**

Yazd

**Postal code****Phone**

+98 35 1822 4000

**Fax****Email**

drfallahzadeh@ssu.ac.ir

**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*