

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**

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Person responsible for scientific inquiries

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Position

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Full name of responsible person

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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