

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Effect of bilinaster drop on the neonatal hyperbilirubinemia in Mashhad Quaem Hospital 1394

#### Protocol summary

##### Summary

Purpose: Effect of bilinaster drop on the neonatal hyperbilirubinemia in Mashhad Quaem Hospital year 1394. design: This study was a randomized controlled clinical trial of two groups. Inclusion criteria: Gestational age 35-42 week, Serum total bilirubin >17 mg /dl or is reached to phototherapy in the hospital based on American Academy of Pediatrics guidelines, birth weight >2000 grams, exclusively breast feeding. Exclusion criteria: the risk of hemolysis or infection, signs of kernicterus , direct bilirubin>2mg/dl, the need for blood exchange, history of any treatment for jaundice before hospitalization. Study population: All nearly or full-term neonates who admitted to Mashhad Quaem Hospital, and they have inclusion criteria. Sample size: 100 neonate 2 to 14 days. interventions: The first group (control) will be received standard treatment (phototherapy ) and the second group (intervention) will be treated with phototherapy and Bilinaester drop by five drops per kg three times a day. Serum billirubin level was assayed on arrival at the hospital, 12 hr, 24 hr, 36 and 48 hrs after treatment. . And measuring of bilirubin will be continued until the baby is discharged.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015050622115N1**  
Registration date: **2015-07-26, 1394/05/04**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-07-26, 1394/05/04

##### Registrant information

##### Name

Zahra Ameli

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 514446070

##### Email address

ameliz1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Sabzevar University of Medical Sciences

##### Expected recruitment start date

2015-06-22, 1394/04/01

##### Expected recruitment end date

2016-01-05, 1394/10/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of bilinaster drop on the neonatal hyperbilirubinemia in Mashhad Quaem Hospital 1394

##### Public title

Effect of bilinaster drop on the neonatal jaundice

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Gestational age 35-42week, birth weight over 2000 grams, total bilirubin>17mg/dl . exclusively breast feeding, lack of photo therapy or other therapies before hospitalisation, jaundice with unknown cause (idiopathic), birth Apgar score>7. Exclusion criteria: Jaundice with known cause (pathological). direct

bilirubin >2, Indications for blood exchange transfusion, severe congenital defects, eclampsia / preeclampsia, asphyxia, transient or mild respiratory distress , sepsis ,hemolytic hyperbilirubinemia

#### Age

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

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **100**

#### 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

Sabzevar University of Medical Sciences

##### Street address

Building Number one, Vice Chancellor for Research & Technology, Sabzevar University of Medical Sciences and Health Services

##### City

Sabzevar

##### Postal code

9613873136

##### Approval date

2015-05-25, 1394/03/04

##### Ethics committee reference number

ك پ 3/199

## 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 bilirubin

#### Timepoint

Before the intervention, then every 12 hours for 48 hours after the intervention

#### Method of measurement

The hospital laboratory and by device autoanalyzer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the control group, only use of standard treatment (phototherapy) .

#### Category

Treatment - Other

### 2

#### Description

In the intervention group, in addition to standard therapy, use of Bilinaster drop 5gtt/kg three times a day.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Mashhad Quaem Hospital

##### Full name of responsible person

Hasan Boskabadi

##### Street address

Ahmadabad street, Quaem Health Education and Research Center, Mashhad

##### City

Mashhad

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Mr. Musa Al-Reza Tadayyon Far

##### Street address

Building number two, Vice Chancellor for Education, Sabzevar University of Medical Sciences and Health Services

**City**  
Sabzevar  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Sabzevar 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**  
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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*