

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 2026

### Comparison of therapeutic effect of Phototherapy with bilineaster and Phototherapy alone in the treatment of neonatal jaundice

#### Protocol summary

##### Summary

This study is aimed to compare the therapeutic effect of Phototherapy with bilineaster and Phototherapy alone in the treatment of neonatal jaundice. Healthy term breast-fed infants weighing 2.5 to 4 Kg that have developed jaundice after 36 hours to 14 days and just need to phototherapy are enrolled and infants with any malformations and associated diseases such as sepsis, ABO or RH incompatibility and direct hyperbilirubinemia and who need Intensive phototherapy or exchange are excluded from study. One hundred fifty neonates with hyperbilirubinemia who were admitted at neonatal ward after entering the study are randomly divided into case and control groups. Infants in each group is 75. Control group only treated with phototherapy but Intervention group received Bilineaster 5 drops per kg of body weight three times a day in addition to the phototherapy. Phototherapy continues to reach bilirubin level of 10 mg / dl and then the babies are discharged from the hospital. Daily bilirubin levels and mean levels of bilirubin in the first day to the last day of the two groups are measured and compared. The mean duration of hospitalization is calculated and compared in both groups. We anticipate bilineaster is effective in the treatment of jaundice, leading to a reduction in the duration of phototherapy and hospital stay .

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013110710933N2**

Registration date: **2014-05-12, 1393/02/22**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2014-05-12, 1393/02/22

##### Registrant information

###### Name

Fatemeh Eghbalian

###### Name of organization / entity

Hamadan University of Medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1822 3978

###### Email address

eghbalian@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Hamadan University of Medical Sciences

##### Expected recruitment start date

2015-05-01, 1394/02/11

##### Expected recruitment end date

2015-05-01, 1394/02/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of therapeutic effect of Phototherapy with bilineaster and Phototherapy alone in the treatment of neonatal jaundice

##### Public title

Evaluation of bilineaster effects in the treatment of neonatal jaundice

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: Healthy term breast-fed infants

weighing 2.5 to 4 Kg after 36 hours until 14 days developed jaundice and phototherapy indicated. Exclusion criteria:pre-and post term infants, formula feeding, the presence of any malformations and associated diseases such as sepsis,weighing less than 2.5 and more than 4 kg; neonates developed jaundice after 14 days, who need Intensive phototherapy or exchange ; ABO or RH incompatibility ;presence direct hyperbilirubinemia

**Age**

No age limit

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: **150**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Hamadan University Of Medical Science

**Street address**

Shahid Fahmide Ave,Hamadan University Of Medical Science, Hamedan, Iran

**City**

Hamedan

**Postal code**

6516837634

**Approval date**

2014-02-01, 1392/11/12

**Ethics committee reference number**

16/35/9/3569/پ/د

**Health conditions studied****1****Description of health condition studied**

Neonatal jaundice

**ICD-10 code**

P59.8

**ICD-10 code description**

Neonatal jaundice from other specified causes

**Primary outcomes****1****Description**

Indirect bilirubin

**Timepoint**

During 24, 48 and 72 hours after beginning of phototherapy

**Method of measurement**

Measuring serum bilirubin(diazo method)

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

Age

**Timepoint**

Between 2 and 14 days of old age

**Method of measurement**

Since birthday

**2****Description**

Duration of hospitalization

**Timepoint**

24,48 and 72 hours after phototherapy

**Method of measurement**

days

**3****Description**

Sex

**Timepoint**

Beginning of study

**Method of measurement**

Physical examination

**4****Description**

Blood group

**Timepoint**

Beginning of study

**Method of measurement**

Laboratory test

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

One hundred fifty neonates with hyperbilirubinemia who were admitted at neonatal ward of Besat hospital of

Hamedan, Iran and who are breast-fed were divided to two groups. seventy five neonates in intervention group received Bilinester 5 drops per kg of body weight three times a day in addition to the phototherapy

**Category**

Treatment - Drugs

**2****Description**

One hundred fifty neonates with hyperbilirubinemia who were admitted at neonatal ward of Besat hospital of Hamedan, Iran and who are breast-fed were divided to two groups. seventy five neonates in control group received phototherapy alone

**Category**

Early detection

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

Besat hospital

**Full name of responsible person**

Dr. Fatemeh Eghbalian

**Street address**

Neonatal ward, Besat Hospital, Fatemieh Ave.

**City**

Hamedan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hamadan University Of Medical Sciences

**Full name of responsible person**

Dr. Fatemeh Eghbalian

**Street address**

Fatemieh ave, Besat Hospital, Hamedan, Iran

**City**

Hamedan

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

Yes

**Title of funding source**

Hamadan 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**

Hamedan University of medical science

**Full name of responsible person**

Dr. Fatemeh Eghbalian

**Position**

Professor

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

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**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*