

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### A comparative study of the effect of Bilynaster and Billy Cuttermana on decreasing jaundice in neonates

#### Protocol summary

##### Summary

This study is aimed to compare the therapeutic effect of Phototherapy with Bili Cuttermana and Phototherapy alone and Phototherapy with bilinaster in the treatment of neonatal jaundice. 350 neonates with hyperbilirubinemia who were admitted at neonatal ward after entering the study are randomly divided into six case and one control groups. Infants in each group are 50. Control group only treated with phototherapy but Intervention group one, infant received Bili Cuttermana 5 drops per kg of body weight three times a day in addition to the phototherapy. Group two, infant received Bilineaster 5 drops per kg of body weight three times a day in addition to the phototherapy. Group three, infant and her/his mother received Bilikatermana 2 drops per kg of body weight three times a day in addition to the phototherapy (infant). Group four, infant and her/his mother received Bilineaster 2 drops per kg of body weight three times a day in addition to the phototherapy (infant). Group five, infants mother received Bili Cuttermana 5 drops per kg of body weight three times a day in addition to the phototherapy (infant). Group six, infants mother received Bilineaster 5 drops per kg of body weight three times a day in addition to the phototherapy (infant). Daily bilirubin levels and mean levels of bilirubin in the first day to the last day (to reach bilirubin level of 10 mg / dl) of the two groups are measured and compared. The mean duration of hospitalization is calculated and compared in both groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015120425203N2**

Registration date: **2016-02-18, 1394/11/29**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-02-18, 1394/11/29

##### Registrant information

###### Name

Hamidreza Aghababaeian

###### Name of organization / entity

Dezful University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 4242 9733

###### Email address

aghababaeian.h@dums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Dezful University of Medical Sciences

##### Expected recruitment start date

2016-02-20, 1394/12/01

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study of the effect of Bilynaster and Billy Cuttermana on decreasing jaundice in neonates

##### Public title

The survey of the effect of Billy Cuttermana on decreasing jaundice in neonates

##### 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 photo therapy indicated.  
Exclusion criteria: per-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 photo therapy or exchange; ABO or RH incompatibility; presence direct hyper bilirubinemia.

## 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: **350**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Dezful University of Medical Sciences

##### Street address

Next to the Police Department, Azadegan Blv, Dezful  
University of Medical Sciences, Dezful, Khozestan,  
Iran

##### City

Dezful

##### Postal code

##### Approval date

2015-08-21, 1394/05/30

##### Ethics committee reference number

lr.dums.rec.1394.9

## 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

Bilirubin

#### Timepoint

On arrival at the hospital, 12, 24, 48, 72 hours after it

#### Method of measurement

Bailey Test milligrams per deciliter

## Secondary outcomes

### 1

#### Description

Bilirubin

#### Timepoint

12, 24, 48, 72 hours after it

#### Method of measurement

Bailey Test milligrams per deciliter

## Intervention groups

### 1

#### Description

Control group only treated with photo therapy

#### Category

Early detection

### 2

#### Description

Intervention group one, infant received Bilikatermana 5 drops per kg of body weight three times a day in addition to the phototherapy

#### Category

Treatment - Drugs

### 3

#### Description

Group two, infant received Bilineaster 5 drops per kg of body weight three times a day in addition to the phototherapy

#### Category

Treatment - Drugs

### 4

#### Description

Group three, infant and her/his mother received Bilicatermana 2 drops per kg of body weight three times a day in addition to the phototherapy (infant)

#### Category

Treatment - Drugs

**5**

**Description**

Group four, infant and her/his mother received Bilineaster 2 drops per kg of body weight three times a day in addition to the phototherapy (infant)

**Category**

Treatment - Drugs

**6**

**Description**

Group five, infants mother received Bilikatermana 5 drops per kg of body weight three times a day in addition to the phototherapy (infant)

**Category**

Treatment - Drugs

**7**

**Description**

Group six, infants mother received Bilineaster 5 drops per kg of body weight three times a day in addition to the phototherapy (infant)

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Dezful Hospital, Dezful University Of Medical Sciences

**Full name of responsible person**

Feridon Nirozad

**Street address**

Next to the Police Department, Azadegan Blv, Dezful University of Medical Sciences, Dezful, Khozestan, Iran

**City**

Dezful

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Dezful University Of Medical Sciences

**Full name of responsible person**

Feridon Nirozad

**Street address**

Next The Police Department, Azadegan Blv, Dezful University of Medical Sciences, Dezful, Khozestan, Iran

**City**

Dezful

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Dezful 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**

Dezful University Of Medical Sciences, Dezful, Iran

**Full name of responsible person**

Hamidreza Aghababaeian

**Position**

Faculty Member

**Other areas of specialty/work**

**Street address**

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**Person responsible for scientific inquiries**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Dezful University Of Medical Sciences, Dezful, Iran

**Full name of responsible person**

Hamidreza Aghababaeian

**Position**

Faculty Member/ Master degree

**Other areas of specialty/work****Street address**Next to the Police Department, Azadegan Blv, Dezful  
University of Medical Sciences, Dezful, Khozestan,  
Iran**City**

Dezful

**Postal code****Phone****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*