

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

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Person responsible for scientific inquiries

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Name of organization / entity

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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
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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*