Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparative study of the effect of Billynaster 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
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Iran (Islamic Republic of)
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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 Billynaster 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
Ir.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
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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
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Person responsible for scientific inquiries

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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