

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

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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