Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Fatemeh Eghbalian
Name of organization / entity
Hamadan University of Medical sciences
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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 Univercity Of Medical Sciencse

Street address
Shahid Fahmide Ave,Hamadan Univercity Of Medical Sciencse, Hamedan, Iran

City
Hamedan

Postal code
6516837634

Approval date
2014-02-01, 1392/11/12

Ethics committee reference number
16/35/9/3569/د/پ

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 groupreceived Bilineaster 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

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Email

eghbalian@umsha.ac.ireghbalian_fa@yahoo.com

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