Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of bilinaster drop on the neonatal hyperbilirubinemia in Mashhad Quaem Hospital 1394

Protocol summary

Summary

Purpose: Effect of bilinaster drop on the neonatal hyperbilirubinemia in Mashhad Quaem Hospital year 1394. design: This study was a randomized controlled clinical trial of two groups. Inclusion criteria: Gestational age 35-42 week, Serum total bilirubin >17 mg /dl or is reached to phototherapy in the hospital based on American Academy of Pediatrics guidelines, birth weight >2000 grams, exclusively breast feeding. Exclusion criteria: the risk of hemolysis or infection, signs of kernicterus , direct bilirubin>2mg/dl, the need for blood exchange, history of any treatment for jaundice before hospitalization. Study population: All nearly or full-term neonates who admitted to Mashhad Quaem Hospital, and they have inclusion criteria. Sample size: 100 neonate 2 to 14 days. interventions: The first group (control) will be received standard treatment (phototherapy) and the second group (intervention) will be treated with photothrapy and Bilinaester drop by five drops per kg three times a day. Serum billirubin level was assayed on arrival at the hospital, 12 hr, 24 hr, 36 and 48 hrs after treatment. . And measuring of bilirubin will be continued until the baby is discharged.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050622115N1**
Registration date: **2015-07-26, 1394/05/04**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-26, 1394/05/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-01-05, 1394/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of bilinaster drop on the neonatal hyperbilirubinemia in Mashhad Quaem Hospital 1394

Public title

Effect of bilinaster drop on the neonatal juandice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age 35-42week, birth weight over 2000 grams, total bilirubin>17mg/dl . exclusively breast feeding, lack of photo therapy or other therapies before hospitalisation, jaundice with unknown cause (idiopathic), birth Apgar score>7. Exclusion criteria: Jaundice with known cause (pathological). direct

bilirubin >2, Indications for blood exchange transfusion, severe congenital defects, eclampsia / preeclampsia, asphyxia, transient or mild respiratory distress , sepsis ,hemolytic hyperbilirubinemia

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: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Sabzevar University of Medical Sciences

Street address
Building Number one, Vice Chancellor for Research & Technology, Sabzevar University of Medical Sciences and Health Services

City
Sabzevar

Postal code
9613873136

Approval date
2015-05-25, 1394/03/04

Ethics committee reference number
199/3/ك پ ژ

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
total bilirubin

Timepoint
Before the intervention, then every 12 hours for 48 hours after the intervention

Method of measurement
The hospital laboratory and by divice autoanalyzer

Secondary outcomes

empty

Intervention groups

1

Description
In the control group, only use of standard treatment (phototherapy) .

Category
Treatment - Other

2

Description
In the intervention group, in addition to standard therapy,use of Bilinaster drop 5gtt/kg three times a day.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad Quaem Hospital

Full name of responsible person
Hasan Boskabadi

Street address
Ahmadabad street, Quaem Health Education and Research Center, Mashhad

City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sabzevar University of Medical Sciences

Full name of responsible person
Mr. Musa Al-Reza Tadayyon Far

Street address
Building number two, Vice Chancellor for Education, Sabzevar University of Medical Sciences and Health Services

City
Sabzevar
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzevar 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
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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