Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison the Effect of Syntetice Purgative Manna Drop and Massage on Neonatal Jundic under Photothropy

Protocol summary

Summary

Purpose: Comparison the effect of Syntetice Purgative Manna drop (Bilinaester drop) and massage therapy on neonatal bilirubin that were under treatment of phototherapy. Design: This study was a randomized controlled clinical trial of three groups (one control and two intervention groups). Inclusion criteria: gestational age 35-42 week, Serum total bilirubin 12-24 mg /dl, birth weight >2000 grams. Exclusion criteria: infection, asphyxia, Indications for blood exchange. Study population: All nearly or full-term neonatales that they have inclusion criteria. Sample size: 72 neonate 2 to 15 days. interventions: The first group (control) will be received standard treatment (phototherapy). The second group (Bilinaester drop intervention) will be treated with photothrapy and Bilinaester drop by three drops per kg three times a day. In third group (massage intervention) infants received " Field" massage in addition to conventional phototherapy." Field" Massage was performed thrice daily (morning، noon and afternoon) for 15 minutes each and after feeding. Before the massage, the hands of the researcher were warmed to the body temperature of the infant.this technique included three steps each lasting five minutes. During the first and final stages, the infant was placed in prone position, and each minute one of the following areas was massaged: A) 12 massage moves (every five seconds one move) from head downwards (both sides of the face to neck and reversely); B) 12 massage motions from the neck to the shoulders and reversely; C) 12 massage moves from the upper back down to the waist and reversely; D) 12 massage moves from the thighs down to the ankles and reversely; E) 12 massage motions from the shoulders to the wrists and reversely, in the middle phase, the infant was put in supine position and six extension and flexion moves were done (10 seconds for each) in the right arm, left arm, right leg, left leg, and both legs. phototherapy devices were randomly used in the cases and control groups. main outcome measures: Serum billirubin level was assayed on arrival at the hospital. Then daily measuring of bilirubin will be continued until the baby is discharged.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016101830370N1**
Registration date: **2016-11-14, 1395/08/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-11-14, 1395/08/24

Registrant information

Name
Fateme Pasban
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 3859 1513
Email address
pasbanf911@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-04-20, 1395/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Effect of Syntetice Purgative Manna Drop and Massage on Neonatal Jundic under Photothropy

Public title

Comparison the Effect of Syntetice Purgative Manna Drop and Massage on Neonatal Jundic under Photothropy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age 35-42 week, birth weight over 2000 grams, total bilirubin12-24 mg/dl. Exclusion criteria: Indications for blood exchange transfusion, infection, asphyxia

Age

From **2 days** old to **15 days** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **72**

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

Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, Daneshgah St

City

Mashhad

Postal code

Approval date

2015-12-05, 1394/09/14

Ethics committee reference number

940442.1.852

Health conditions studied

1

Description of health condition studied

neonatal hyperbilirubinemia

ICD-10 code

59.9

ICD-10 code description

Neonatal Jaundice

Primary outcomes

1

Description

Unknown Hyperbilirubinemia

Timepoint

At admision

Method of measurement

Questionnaire, Laboratory Test

Secondary outcomes

1

Description

Bilirubine level

Timepoint

At admision, phototherapy, discharge time

Method of measurement

At admision, phototherapy, discharge time

Intervention groups

1

Description

control group: neonatal will be received only phototherapy and standard treatment

Category

Treatment - Other

2

Description

massage intervention group: infants will be received " Field" massage in addition to conventional phototherapy." Field" Massage was performed thrice daily (morning، noon and afternoon) for 15 minutes each and after feeding. Before the massage, the hands of the researcher were warmed to the body temperature of the infant.this technique included three steps each lasting five minutes. During the first and final stages, the infant was placed in prone position, and each minute one of the following areas was massaged: A) 12 massage moves (every five seconds one move) from head downwards (both sides of the face to neck and reversely); B) 12 massage motions from the neck to the shoulders and

reversely; C) 12 massage moves from the upper back down to the waist and reversely; D) 12 massage moves from the thighs down to the ankles and reversely; E) 12 massage motions from the shoulders to the wrists and reversely, in the middle phase, the infant was put in supine position and six extension and flexion moves were done (10 seconds for each) in the right arm, left arm, right leg, left leg, and both legs.

Category

Treatment - Other

3

Description

Bilinaester drop intervention group: Neonatal will be treated with photothrapy and Bilinaester drop by three drops per kg three times a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Birjand Valeasr Hospital

Full name of responsible person

Gharaei docter

Street address

Childeren Unit, Valeasr Hospital, Ghafari st

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi, Vice chancellor for research

Street address

Vice chancellor for research، Mashhad University of Medical Sciences, Daneshgah St

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Fateme Pasban

Position

Student of Master of Sciences in Nursing Neonatal Intensive Care

Other areas of specialty/work

Street address

Nursing of college, Daneshgah St

City

Mashhad

Postal code

Phone

+98 51 3859 1513

Fax

+98 51 3859 1513

Email

pasbanf911@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Tayebe Rahani

Position

Master of Sciences

Other areas of specialty/work

Street address

Nursing of college, Daneshgah St

City

Mashhad

Postal code

Phone

+98 51 3859 1513

Fax

+98 915 122 9727

Email

rahanit@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Tayebe Rahani

Position
Master of Sciences
Other areas of specialty/work
Street address
Nursing of college, Daneshgah St
City
Mashhad
Postal code
Phone
+98 51 3859 1513
Fax
+98 915 122 9727
Email
rahanit@mums.ac.ir
Web page address

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