Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of two Massage Techniques, Field and Vimala, on reduction of Physiological Jaundice in Term and Late Preterm Infants: A Single-blind Clinical Trial

Protocol summary

Summary

The aim of this study is to compare the effect of two message techniques, field and vimala, on jaundice in term and late preterm infants. About 100 eligible infants (over 35 weeks gestational age, weighing between 2000-4000g, apgar score between 8-10 for first minute and fifth minute) will be randomly divided into three groups. The subjects in first group will be messaged in accordance with field message technique, 3 times a day for 15 minutes with use of sunflower oil for 4 days from the birth. In the second group, the subjects will be messaged same as first group but in accordance with Vimala message technique. The subjects in third group will receive routine care and no intervention will be performed on them. The infants which require phototherapy due to elevated billirubin level or receive billirubin-lowering drugs will be excluded. During study, the researcher will record all information relating to infant include, skin and serum level of bilirubin, time of the first excretion of meconium and numbers of stools and feedings per day. Reducing the billirubin level, has considered as primary outcome in this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204116918N8**
Registration date: **2012-08-09, 1391/05/19**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-08-09, 1391/05/19

Registrant information

Name

Alehe Seyedrasooli

Name of organization / entity

Faculty of Nursing & Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 41 1479 0365

Email address

seyyedrasooly@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Tabriz University of Medical Sciences, Tabriz University of Medical Sciences,Tabriz, Iran

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two Massage Techniques, Field and Vimala, on reduction of Physiological Jaundice in Term and Late Preterm Infants: A Single-blind Clinical Trial

Public title

massage effect and jaundice

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: over 35 weeks gestational age; weighing between 2000-4000g; apgar score between

8-10 for first minute and fifth minute; having no congenital disease and problems such as neonatal asphyxia, ecchymosis, birth trauma, congenital infection. exclusion criteria: starting phototherapy in result of elevated total billirubin level; recieving billirubin-lowering drugs.

Age
From **1 year** old to **4 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size:

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
Tabriz University of Medical Science

Street address
Central Building of Tabriz University of Medical Sciences,Golgasht Avenue, azadi street,Tabriz

City
Tabriz

Postal code

Approval date
2012-04-20, 1391/02/01

Ethics committee reference number
9163

Health conditions studied

1

Description of health condition studied
neonatal Physiological jaundice

ICD-10 code
P59.9

ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
reduction of billirubin level

Timepoint
during study, daily

Method of measurement
in mg/dl with use of cutaneous and blood test

Secondary outcomes

1

Description
stool frequency

Timepoint
daily

Method of measurement
observation

Intervention groups

1

Description
The newborns in control group will receive routine care and no intervention will be performed on them.

Category
N/A

2

Description
In first group tactile and kinesthetic stimulation will carry out in 15-minute sessions.Each session consisted of 3 standardized phases of 5 minutes each, in which the infants were keep in a prone position in the 1st and 3rd phase. The neonates will gently stroke with the soft, smooth surfaces of all the fingers of both hands. The tactile stimulation procedure included 12 strokes at a rate of approximately 5 seconds per stroking motion over each region of the neonate in the following sequence: From the top of the head down the sides of the face to the neck, and vice versa; From the back of the neck to both ends of the shoulders, and vice versa; From the thighs down to the ankles, and vice versa; From the shoulders down the arms to the wrist, and vice versa In the middle phase, the neonate will make to lie in a supine position for kinesthetic stimulation that included 5 segments of 1 minute each which consist of 6 passive flexion/extension movements, each lasting 10sec. The stimulation will do on each arm, then each leg and lastly both legs together.

Category
Prevention

3

Description
In second group; massage will carry out in 15-minute

sessions; Each session consisted of 2 standardized phases. First phase in supine position; Face: Gently massage upper lids with your thumbs outward, from the nose to the cheeks; slide your thumbs from the upper lip to the cheeks; then under the ears with index and middle finger from ears the chin; Arms and hands: Gently massage the armpit with circular movements; slide your hands from the shoulder to the wrists; use twisting movements in opposite direction; Chest: Slide both hands starting from the midline to the sides, from the sides to midline. Abdomen: Slide hand down the abdomen, alternating left and right; slide hands together from right to left over the abdomen. Slide your hands downward on the left side, upward on the right side of the abdomen, then over the belly and bottom and coming down on the left side (inverted U). Slide fingertips of both hands over the abdomen, from right to left. Legs and feet: Slide your hands from the thigh to the ankle, with twisting movements in opposite directions over thigh, leg, and foot; slide hands from ankle to thigh with ascending movements. Finally, turn the child facedown. Slide both hands from the back of the neck to the hips from top to bottom, alternating. Slide your hands from side to side in opposite directions; with the index and middle finger draw circles from top to bottom following the spine

Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Educational Center Affiliated Tabriz university of Medical Sciences ;Iran
Full name of responsible person
mohammadzad somayye
Street address
Bagshomal Square
City
tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy of Tabriz University of Medical Sciences
Full name of responsible person
Dr. Rashidi
Street address
Central Building of Tabriz University of Medical Sciences,Golgasht Avenue, azadi street,Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy of Tabriz 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

Person responsible for scientific inquiries

Contact
Name of organization / entity
Faculty of Nursing & Midwifery of Tabriz
Full name of responsible person
Seyedrasooli Alehe
Position
MS
Other areas of specialty/work
Street address
South Shariety St ; Faculty of Nursing & Midwifery ; Tabriz ; Iran
City
Tabriz
Postal code
Phone
+98 41 1479 0365
Fax
Email
seyyedrasooly@tbzmed.ac.ir
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*