Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The Effect of Massage on Neonatal Hyperbilirubinemia in Neonatal Intensive Care Unit

Protocol summary

Study aim

Determining the effect of massage on Hyperbilirubinemia in infants admitted to the neonatal intensive care unit

Design

Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site.

Settings and conduct

This clinical trial study was conducted in two intervention and control groups on 70 admitted infants in the intensive care unit. Eligible babies will be assigned to intervention and control groups using the random block. Both mothers and infants mothers will be given individual education about breastfeeding and jaundice. Control neonates will receive only routine care. However, the newborns in the intervention group will be massaged in addition to receiving usual care for 5 days, 3 times a day, and 15 minutes each, based on the technique of Fidel's mother (after training by the researcher). The amount of skin infant bilirubin (Coutaneus Billirubin Trans = TCB) is measured daily for five days (although the measurement of bilirubin is not due to research, but according to the routine of the hospital for newborns with jaundice on a daily basis), the first time the meconium is excreted and The number of meconium in 24 hours and in both groups is recorded for five days. During the study, the person receiving the bilirubin level is blind to the groups.

Participants/Inclusion and exclusion criteria

Infants with fetal age 37 to 42 weeks without congenital anomalies. Lack of knowledge of known gastrointestinal and central nervous system problems. Babies weighing over 2500 to 4000 grams. Babies with a one-day age who are not hospitalized at least until the fifth day of birth, and do not have a massage ban.

Intervention groups

Neonates with Hyperbilirubinemia who are admitted to the intensive care unit

Main outcome variables

Evaluation of blood bilirubin reduction in patients in control and intervention groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150621022852N2**
Registration date: **2018-02-20, 1396/12/01**
Registration timing: **retrospective**

Last update: **2018-02-20, 1396/12/01**
Update count: **0**

Registration date

2018-02-20, 1396/12/01

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44429613

Email address

dr.s.asaadi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Massage on Neonatal Hyperbilirubinemia in Neonatal Intensive Care Unit

Public title
The Effect of Massage on Neonatal Jundice in Neonatal Intensive Care Unit
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Noramal Birth Weight:2500 to 4000 grams No history of any acute congenital disorder Negative symptom or sign of Sepsis or infection
Exclusion criteria:
Age
From **1 day** old to **5 days** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of random sampling is blocking. To determine whether each child is in the control group or experience the use of the blu-ring method, it is determined by the throwing of the six-sided dice that controls or experiences from the first to the last one. To implement the blocking method, two modes A and B are considered so that the six blocks are as follows from the different types of placement of these two modes together: 1)ABAB 2)AABB 3) ABBA 4)BBAA 5)BABA 6) BAAB Then, with the throwing of six-sided dice, ten blocks of four (ten modes for the direction of 70 children) are obtained randomly according to the above conditions; each of the selected letters will be considered for children 1-42. A and B modes are also determined randomly (lottery) as controls or as experiences (eg, mode A as control and B as experience). In addition, with the throw of dice, the order of the block is specified. Draw and throw dice in the presence of a supervisor or consultant professor. Examples of dice throwing scenarios, for example, are achieved, and the following results are obtained and the assignment of samples to the experiment group and control will be based on it.
Blinding (investigator's opinion)
Single blinded
Blinding description
A person who performs the Blilirubin test will be Blind to the groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Poursina st,Enghelab Ave,Tehran,Iran
City
Tehran
Province
Tehran
Postal code
34252523525
Approval date
2017-06-19, 1396/03/29
Ethics committee reference number
IR.TUMS.FMN.REC.1396.2684

Health conditions studied

1

Description of health condition studied
Hyper bilirubinemia
ICD-10 code
P59.9
ICD-10 code description
Neonatal jaundice, unspecifiedPhysiological jaundice (intense)(prolonged) NOS

Primary outcomes

1

Description
level of bilirubin in serum
Timepoint
in first five days of intervention
Method of measurement
Measurement of serum bilirubin levels in blood samples of patients.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The intervention group of the

newborns in the intervention group, in addition to receiving usual care, will be given massage for a period of five days, 3 times a day, and 15 minutes each time, according to the technique of the Fidel Massage. The practice of massage is taught to mothers by the trained researcher in accordance with the guidelines of the International Association of Infant Massage (IAIM). Babies will be massaged during the first day by a researcher or mother's participation. After assessing and assuring the mother's learning and mastery of massage; Mothers from the first to fifth days do their massage therapy on their babies, and their performance is monitored by the researcher in a timely and correct manner. Massage after washing and Warming the hands is done in a warm environment.Each massage is composed of 3 phases of 5 minutes and a total of 15 minutes. In the first and third phases, the baby is placed in the abdomen and the massage is done as follows: 1) from the top to the neck and vice versa, 2) From the neck to the shoulders and vice versa, 3) from the back to the waist and vice versa, 4) from the shoulder to the hand, then in the direction of return in both hands, 5) from the thigh to the ankle and then in the direction of return in both Leg. In the second stage, motor stimulation involves extensibility and flexion of the organs in the supine position.

Category

Treatment - Other

2

Description

Control group: In the control group after birth and transfer to the neonatal ward, they will be evaluated and qualified to join the study by researchers.Then, the goal of the study will explained to mothers and after obtaining consent and completing the informed consent form they will be enrolled in study. All mother will be inform about breastfeeding and jaundice. The control group will receive only routine care, such as umbilical cord care, audiometry, and vaccination. During study days control group will be assess about same study variables that will be check in intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Hospital

Full name of responsible person

Zeinab Shokati mir

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Eastern 162th St.,3rd Sq.,Tehran Pars District 4, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Zeinab Shokati Mir

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
Data from the study under the supervision of the scientific and practical scientist will be the study of collecting and sharing the results and raw data with full supervision.
When the data will become available and for how long
From the beginning of the study to the publication of the results.
To whom data/document is available
Researcher and supervisor of the plan and the officials of the Ethics Committee of the University
Under which criteria data/document could be used
To verify the results and verify the accuracy of the documentation.
From where data/document is obtainable
Must be referred to the scientific and practical planner.
What processes are involved for a request to access data/document
Call the scientific and practical scientist through the phone or email.
Comments