Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

effect of massage on neonatal hyperbilirubinemia

Protocol summary

Study aim

1) Determining the effect of massage on hyperbilirubinemia in newborns 2) Comparison of the average bilirubin on the first day in the control and intervention groups 3 Comparison of the average bilirubin on the second day in the control and intervention groups 4) Comparison of the average bilirubin on the third day in the control and intervention groups 5) Comparison of the average weight of hospitalized infants in the control and intervention groups 6) Comparing the stool frequency of infants in the control and intervention groups 7) Comparison of hospitalization time of infants in two control and intervention groups

Design

A clinical trial with a control group, double-blind, non-expert, randomized in pairs and odd

Settings and conduct

The location of the project of Tehran Bahrami Hospital In this study, babies are divided into two groups, control and intervention. The control group is treated with phototherapy only for the treatment of hyperbilirubinemia. In the intervention group, massage is performed twice a day at certain times, 30 minutes after feeding for 15 minutes, once by the student and once by the mother for 3 days. In this study, 25 people are considered as the control group and 25 people as the intervention group. In these children, bilirubin, baby weight, frequency of urination and defecation and temperature are checked daily.

Participants/Inclusion and exclusion criteria

1) The weight of children should be between 2.5-4 kg 2) Pathological jaundice in these babies is more than 12mg/dl. 3) Gestational age more equal to 37 weeks 4) Babies more than 48 hours

Intervention groups

In the intervention group, massage is performed 2 times a day at specific times 30 minutes after breastfeeding for 15 minutes once by the student and once by the mother for 3 days.

Main outcome variables

bilirubin stool frequency Length of hospitalization Weight

General information

Reason for update

Update in the start and end date of the expected and actual recruitment

Acronym

IRCT registration information

IRCT registration number: **IRCT20110420006243N4**
Registration date: **2022-12-16, 1401/09/25**
Registration timing: **prospective**

Last update: **2024-10-28, 1403/08/07**
Update count: **1**

Registration date

2022-12-16, 1401/09/25

Registrant information

Name
Shiva Rafati

Name of organization / entity
Shahed university

Country
Iran (Islamic Republic of)

Phone
+98 21 8896 9437

Email address
rafati@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-17, 1401/09/26

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

2022-12-22, 1401/10/01

Actual recruitment end date

2023-02-20, 1401/12/01

Trial completion date

2023-02-24, 1401/12/05

Scientific title

effect of massage on neonatal hyperbilirubinemia

Public title

effect of massage on neonatal jaundice

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

hyperbilirubinemia more than 12 mg/dl weight between 2/5-4 kg gestational age more than 37

Exclusion criteria:

Babies less than 48 hours A baby who is dehydration, does not feed well, is lethargic. A baby with sepsis, seizures, hypoglycemia

Age

From **3 days** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

In the control group, massage is performed without any purpose in addition to phototherapy, which made the participant unaware of the type of participation in the project. The massage is performed once by a doctor and once by the mother, which causes the researcher to be unaware. A data analyst also has no knowledge of the plan. In the test group, targeted massage is performed with a special method in addition to phototherapy.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of shahed university of medical sciences

Street address

Tehran, Shahid Montazeri Street, Memarian Block, Block 5, Unit 5

City

tehran

Province

Tehran

Postal code

1714716653

Approval date

2022-03-08, 1400/12/17

Ethics committee reference number

IR.SHAHED.REC.1400.210

Health conditions studied

1

Description of health condition studied

hyperbilirubinemia

ICD-10 code

P59.9

ICD-10 code description

Neonatal jaundice, unspecified

Primary outcomes

1

Description

The amount of total bilirubin on different days

Timepoint

1) Measurement of bilirubin in the newborn's blood upon entering the study, then on the first, second, and third days after the intervention.

Method of measurement

by laboratory by photometric means using 2 and 4 dichloroaniline

Secondary outcomes

1

Description

Comparison of the average weight of hospitalized infants in the control and intervention groups

Timepoint

When the baby enters the plan and on the first, second and third days after the intervention

Method of measurement

by means of a digital scale and under the same conditions

2

Description

Comparison of infant stool frequency in the control and intervention groups

Timepoint

per day

Method of measurement

Number of diapers changed per day

3

Description

Comparison of hospitalization time of infants in two control and intervention groups

Timepoint

Record the number of days of hospitalization

Method of measurement

With the help of the date of arrival and departure

Intervention groups

1

Description

Intervention group :The intervention group is the group that, in addition to receiving phototherapy, received massage in this group. The massage is done with bare hands without any substance. The massage method is sub-designed: first the hands are washed and dried. The hands warm up the hands and bring them closer to the baby's body temperature. First, we start the massage from the face area and the thumb pad area around the eyes and cheeks with a very calm and low pressure, this work continues in the same way until the chest area. will continue. Then, the massage of the upper and lower limbs continues with a little more pressure than the previous areas. Finally, the baby's back is covered with the pads of the thumbs from the neck to the baby's buttocks. The massage method is the same for all the babies in the intervention group.

Category

Treatment - Other

2

Description

Control group: The control group in this study includes babies who only received phototherapy and no intervention was done for them

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Bahrami hospital

Full name of responsible person

Mohammadjavad Arabzadeh

Street address

Imam Hossein Square - Damavand St. - Shahid Kiyani St., Qasim Abad Station, Bahrami Children's Hospital

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mohammadjavad.arabzadeh123@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Afshin Magd

Street address

Valiasr Square, Keshavarz Blvd., Palestine St., Italy St., plate 9

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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

Shahed University

Proportion provided by this source

10

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

Shahed University

Full name of responsible person

Shiva Rafati

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After the design, the data is collected in an Excel file and archived after the publication of the article and analysis
When the data will become available and for how long
6 months after the project
To whom data/document is available
Pediatrician professors of universities
Under which criteria data/document could be used
The data can be used for university teaching or to validate the plan or meta-analysis for the research subject if the legal conditions of the person are met.
From where data/document is obtainable
To the mentioned address and the person responsible for the plan
What processes are involved for a request to access data/document
Writing a written letter and the reason for requesting the data after approval by the responsible person and with her decision
Comments