Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of massage based on Iranian medicine with almond oil on bilirubin in full-term and pre-term infants with hyperbilirubinemia referred to the phototherapy departments of Shiraz hospitals.

Protocol summary

Study aim

1. Determine and compare the demographic characteristics between term and preterm infants in the intervention and control group 2. Determine and compare the mean of serum bilirubin before massage between the intervention and control groups in full-term and preterm neonates 3. Determine and compare the mean of serum bilirubin changes between term and preterm infants in the intervention and control group 4. Determine and compare the changes in the number of phototherapy days in term and preterm infants in the intervention and control group 5. Determination of predictive variables, bilirubin index in term and premature neonates in the intervention and control group

Design

A non-blinded randomized clinical trial with the control group. In 160 neonates. The online software will use for randomization.

Settings and conduct

Along with the routine care in the intervention group, the mother will massage the Infant for 15 minutes with almond oil three times a day in the phototherapy departments of Shiraz University of Medical Sciences hospitals for three days. Usual care will be done for the control group.

Participants/Inclusion and exclusion criteria

Birth age over 34 weeks and referred to the phototherapy centers. hyperbilirubinemia and no other underlying conditions, absence of infection, receiving medication during the study, and lack of sensitivity to almond oil.

Intervention groups

The massage group -the control group

Main outcome variables

Serum bilirubin level Number of phototherapy days

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221204056708N1**
Registration date: **2022-12-22, 1401/10/01**
Registration timing: **prospective**

Last update: **2022-12-22, 1401/10/01**
Update count: **0**

Registration date

2022-12-22, 1401/10/01

Registrant information

Name

Bahar Morshed-Behbahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3647 4251

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morshe_b@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01

Expected recruitment end date

2023-09-21, 1402/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of massage based on Iranian medicine with almond oil on bilirubin in full-term and pre-term infants with hyperbilirubinemia referred to the phototherapy departments of Shiraz hospitals.

Public title
Investigating the effect of massage based on Iranian medicine on the level of bilirubin in newborns

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Birth age over 34 weeks Hyper bilirubin Hospitalization in the photo therapy department

Exclusion criteria:
Underlying medical conditions medicine consumption sensitivity to almond oil

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the stratified permutation block method will assign neonates to two control and intervention groups in two subgroups. Based on the size of the sample and the number of groups, and considering the two subgroups to create the correct ratio of sample allocation to the blocks, eight blocks of 20 will be allocated in the random allocation list (according to the two subgroups, ten items per subgroup). We will prepare the random allocation list with online software.

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
The Ethics Committee of the Schools of Nursing and Midwifery, Management and Medical Information - S

Street address
Karimkhan Zand Street, Namazi Square

City
Shiraz

Province
Fars

Postal code
7193613119

Approval date
2022-12-20, 1401/09/29

Ethics committee reference number
IR.SUMS.NUMIMG.REC.1401.100

Health conditions studied

1

Description of health condition studied
Neonatal jaundice, unspecified

ICD-10 code
P59

ICD-10 code description
Neonatal jaundice from other and unspecified causes

Primary outcomes

1

Description
Mean serum bilirubin level

Timepoint
Daily , from the time of admission until three days

Method of measurement
Venous blood sampling and measurement of bilirubin level

Secondary outcomes

1

Description
The number of photo therapy hours

Timepoint
Discharge time

Method of measurement
Photo therapy hours recorded in the file

Intervention groups

1

Description
Intervention group: Massage based on Iranian medicine with almond oil. We massage the neonates in 3 stages for 15 minutes. 5 minutes for each step. In the first step: We put the neonate on his abdomen. We will massage the neonate from the top of the head to the neck and upside down. Then back and forth movements from the neck to the shoulders. Then, from the upper back to the waist. Then we massage from the shoulder to the

fingertips back and forth (on both hands). Then massage from the thigh to the ankle in a back-and-forth motion, which we do on both legs. In the second step, we put the baby to sleep in the open arch position. We perform bending and straightening movements of the right arm, left arm, right leg, and left leg (folded or flexed) in each step (opening and closing the hand or leg) movement in ten seconds, which together take one minute will be done. It will take about 5 minutes for both hands and both feet. In the third step, we will repeat the first step. These steps are taught to the mother to perform.

Category
Treatment - Other

2

Description
Control group: In this group, we perform only routine care, such as phototherapy.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat Zainab Hospital

Full name of responsible person
Bahar Morshed Behbahani

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2

Recruitment center

Name of recruitment center
Hafez hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Mahtab Memarpour

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7134814336

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Email
memarpour@sums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Bahar Morshed-Behbahani

Position
Assistant Professor of Reproductive Health MPH of Health Policy

Latest degree
Ph.D.

Other areas of specialty/work
Reproductive Health

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available