Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of two massage-therapy methods on defecation of newborns with indirect hyperbilirubinemia

Protocol summary

Study aim
The purpose of this study is to present an appropriate method of massage therapy as an adjunctive treatment in neonatal indirect hyperbilirubinemia in addition to the main treatment which is photo therapy .which leads to a reduction in the length of hospitalization and the cost of the treatment.

Design
Two arm parallel group randomised trial with postoperative care and outcome assessment

Settings and conduct
This study aims to evaluate the effect of massage therapy as an adjunctive treatment in neonates with indirect hyperbilirubinemia. Eligible infants admitted to the neonatal ward of Mofid Children's Hospital in Tehran are randomly assigned to three groups: a control group receiving phototherapy alone, an abdominal massage group receiving phototherapy plus abdominal massage, and a spinal massage group receiving phototherapy plus spinal massage. Informed consent is obtained from parents prior to enrollment. Each group consists of 30 neonates. Massage techniques, based on international guidelines, are taught to mothers under the supervision of physical medicine specialists. Educational pamphlets are provided in the ward, and nursing staff oversee the proper implementation of the massage procedures.

Participants/Inclusion and exclusion criteria
All neonates with indirect hyperbilirubinemia with gestational age above 37 weeks and birth weight above 2500 gr , which don`t need exchange transfusion or medication as part of treatment and don`t have abdominal or spinal problems

Intervention groups
Neonates who are admitted for photo therapy divide to two group and for each group we use a different method of massage therapy and our control group is neonates that only have photo therapy without massage therapy.

Main outcome variables
Rate of bilirubin decreasing, length of hospitalization, number of stool passage ,cost of treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250622066216N1**
Registration date: **2025-12-04, 1404/09/13**
Registration timing: **registered_while_recruiting**

Last update: **2025-12-04, 1404/09/13**
Update count: **0**

Registration date
2025-12-04, 1404/09/13

Registrant information

Name
Parinaz Alizadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2222 7021

Email address
p.alizadeh@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-22, 1404/07/30

Expected recruitment end date
2025-12-21, 1404/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the effect of two massage-therapy methods on defecation of newborns with indirect hyperbilirubinemia

Public title
Effect of massage therapy on neonatal hyperbilirubinemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Neonates with indirect hyperbilirubinemia admit for phototherapy Birth weight above 2500gr Gestational age above 37 weeks
Exclusion criteria:
Need exchange transfusion Need medication for hyperbilirubinemia treatment Direct hyperbilirubinemia Neonates with abdominal or spinal problems
Age
From **1 day** old to **28 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
N/A
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
Research Ethics Committees Of School Of Medicine-Shahid Beheshti University Of Medical Science
Street address
Third Floor-Medical University-Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2025-10-08, 1404/07/16
Ethics committee reference number
IR.SBMU.MSP.REC.1404.359

Health conditions studied

1

Description of health condition studied
Neonatal indirect hyprerbilirubinemia
ICD-10 code
R17
ICD-10 code description
Unspecified jaundice

Primary outcomes

1

Description
The trend of decreasing indirect bilirubin
Timepoint
Immediately after hospitalization: 6, 12, and 24 hours post-admission
Method of measurement
Measurement of serum bilirubin level by venous blood sampling

2

Description
Frequency of bowel movements
Timepoint
During the entire hospitalization
Method of measurement
Record in file

Secondary outcomes

1

Description
Length of hospital stay
Timepoint
First day of hospitalization - Last day of hospitalization
Method of measurement
The number of days the newborn was hospitalized from the time of admission to the ward until discharge, recorded in the file

2

Description
Hospitalization cost
Timepoint
First day of hospitalization - Last day of hospitalization
Method of measurement
Estimated daily hospitalization cost in the ward based on the calculated expenses of the hospital's financial department

Intervention groups

1

Description
Intervention group1: The Spinal massage therapy group is based on standard guidelines and under the supervision of a physical medicine professor. This massage is performed on hospitalized newborns with hyperbilirubinemia. These newborns receive the main treatment of phototherapy in the ward to reduce jaundice, and abdominal massage therapy is performed as an adjuant treatment during the hospitalization period, three times a day, each time for 15 minutes. The mother is taught how to perform the massages, and a trained nurse also monitors the proper implementation of the massages. All these newborns receive the standard treatment for jaundice, which is phototherapy. The massages are also written on a pamphlet and the steps are taught in simple language.

Category
Treatment - Other

2

Description
Intervention group 2:The abdominal massage therapy group is based on standard guidelines and under the supervision of a physical medicine professor. This massage is performed on hospitalized newborns with hyperbilirubinemia. These newborns receive the main treatment of phototherapy in the ward to reduce jaundice, and abdominal massage therapy is performed as an adjuant treatment during the hospitalization period, three times a day, each time for 15 minutes. The mother is taught how to perform the massages, and a trained nurse also monitors the proper implementation of the massages. All these newborns receive the standard treatment for jaundice, which is phototherapy. The massages are also written on a pamphlet and the steps are taught in simple language.

Category
Treatment - Other

3

Description
Control group: There are babies who are hospitalized in the ward due to hyperbilirubinemia and only receive phototherapy as the main treatment and do not receive any type of massage as an adjunctive treatment.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Childrens Hospital
Full name of responsible person
Parinaz Alizadeh
Street address
No.1146, Shariati Street - above Hosseiniyeh Ershad
City
Tehran
Province
Tehran
Postal code
1551415468
Phone
+98 21 2222 7021
Email
info-mch@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Ali Ziai
Street address
3th Floor, Bldg No.2 SBMU, Arabi Ave, Daneshjoo Blvd, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
193954631
Phone
+98 21 2243 9951
Email
mpd@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parinaz Alizadeh

Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
No.1146, Shariati Street - above Hosseiniyeh Ershad
City
Tehran
Province
Tehran
Postal code
1551415468
Phone
+98 21 2222 7021
Email
p.alizadeh@sbmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parinaz Alizadeh
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
No. 1146, Shariati St-above hosseinieh irshad-Mofid Childrens Hospital
City
Tehran
Province
Tehran
Postal code
1551415468
Phone
+98 21 2222 7021
Fax
Email
p.alizadeh@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parinaz Alizadeh
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
Street address
No.1146, Shariati St-above hosseinieh irshad-Mofid Childrens Hospital
City
Tehran
Province
Tehran
Postal code
1551415468
Phone
+98 21 2222 7021
Fax
Email
p.alizadeh@sbmu.ac.ir

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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data can potentially be shared after individuals are anonymized.
When the data will become available and for how long
Access period starts 6 months after the publication of results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
The request submitted to the Scientific Committee of the Neonatal Research Center will be reviewed and, if approved, will be made available.
From where data/document is obtainable
Contact the project manager Dr. Parinaz Alizadeh at the email address p.alizadeh@sbmu.ac.ir
What processes are involved for a request to access data/document
After sending the request via email, the data will be made available within a maximum of one week if approved by the project manager.
Comments