Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Compratitive investigating the effect of reflexology and neonatal massage on the level of bilirubin in hospitalized neonates with hyperbilirubinemia

Protocol summary

Study aim
Comparison of the effect of two methods of massage and reflexology on the bilirubin level of newborns with hyperbilirubinemia treated with phototherapy admitted in Hospital

Design
This study is a randomized clinical trial with control group and samples will be divided into two intervention groups and one control group.

Settings and conduct
After receiving written consent from the infant's parents, the serum bilirubin level of the infant was obtained by taking the venous blood sample before Phototherapy is determined in all three groups (massage, reflexology and control intervention). Then the amount of bilirubin will be measured again within 24 hours and 48 hours. Neonates receive routine treatment for jaundice (phototherapy) in all three groups. device.

Participants/Inclusion and exclusion criteria
Inclusion criteria are term neonates with indirect hyperbilirubinemia and congenital abnormalities and clear gastrointestinal disorders. Exclusion criteria are any risk factors such as hemolysis, septicemia, asphyxia, pathologic jaundice (day 1 jaundice) and infection

Intervention groups
In the first intervention group, in addition to phototherapy, massage therapy and in the second intervention group, in addition to phototherapy, reflexology will be performed. The control group will receive only phototherapy.

Main outcome variables
Bilirubin level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180206038642N3**
Registration date: **2019-08-30, 1398/06/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-30, 1398/06/08**
Update count: **0**

Registration date
2019-08-30, 1398/06/08

Registrant information

Name
Fatemeh Abdoli

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3425 5900

Email address
abdoli_f@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Compratitive investigating the effect of reflexology and neonatal massage on the level of bilirubin in hospitalized

neonates with hyperbilirubinemia

Public title
The effect of reflexology and massage on neonatal jaundice
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
having indirect hyperbilirubinemia. Term baby (42-37 weeks) Apgar at birth 8-10 Infants weighing at least 2500 grams to 4000 grams No prohibition of foot massage (Edema, tissue damage, skin infections, cutaneous rash, fractures and vascular disorders) Failure to pass meconium
Exclusion criteria:
Any risk factors such as hemolysis, septicemia, asphyxiation Pathologic icter (jaundice of the first day) Glucose 6-phosphate enzyme deficiency (G6PD) Congenital anomalies Infection (pneumonia, gastroenteritis, sepsis and bronchitis) Gastrointestinal obstruction Biliary atresia Diarrhea and child tanning during phototherapy Parental unwillingness to participate in the study disease such as congenital anomalies, neurological disorders, gastrointestinal and genetic disorders Perform blood transfusion
Age
From **3 days** old to **15 days** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be made available, purposeful and gradual. Samples will be randomly divided into two intervention groups (reflexology and massage) and a control group. In order to prevent communication and inform the parents of the three groups, sampling will be done weekly, so that it will first be determined by lottery which groups will be evaluated in the first, second and third weeks. Then sampling will continue until the desired number is reached.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Rafsanjan University of Medical Sciences
Street address
Blvd. Hazrat Ali ibn Abitaleb
City
Rafsanjan
Province
Kerman
Postal code
7718796755
Approval date
2019-05-15, 1398/02/25
Ethics committee reference number
IR.RUMS.REC.1398.029

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 bilirubin
Timepoint
Before the intervention and 24 hours and 48 hours after the intervention
Method of measurement
Laboratory result

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the massage therapy group, babies receive massage programs in addition to phototherapy, for three consecutive days for 20 to 15 minutes a day.
Category
Treatment - Other

2

Description
Intervention group: In the reflexology group, neonates, in addition to phototherapy, according to the study, receive reflexology program for two consecutive days and three times a day, each 20-15 days in the intestine and colon.

Category
N/A

3

Description
Control group: In the control group, only phototherapy will be performed.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Ali Ibn Abi Talib Hospital in Rafsanjan

Full name of responsible person
Negar Nikzad

Street address
Boulevard of Imam Ali ibn Abitaleb

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences

Full name of responsible person
fateme Abdoli

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Rafsanjan 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
Rafsanjan University of Medical Sciences

Full name of responsible person
Fateme Abdoli

Position
Faculty member

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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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
Yes - There is 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
Publish the results through a thesis and a valid scientific journal
When the data will become available and for how long
Max. Up to one year
To whom data/document is available
Medical and Nursing Society
Under which criteria data/document could be used
Use of results in research and clinical applications
From where data/document is obtainable
Via telephone and email
What processes are involved for a request to access data/document
Requests for correspondence will be made upon request
Comments