Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of foot reflexology and body massage on physiological parameters and bilirubin levels in neonates under photo therapy

Protocol summary

Study aim
Comparison of the effect of reflexology and body massage on physiological parameters and bilirubin level in neonates under photo therapy

Design
Single blinded, randomized, parallel group trial with control group, without placebo, multi-centered.

Settings and conduct
This randomized clinical trial carried out on 51 neonates with jaundice in Imam Hossein Pediatric Medical Center, Goldis Hospital of Shahin Shahr and Asgarieh Hospital of Isfahan. Participants and data analyzer will not know allocation of samples to interventions and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: no underlying, congenital and infectious diseases; term infants (gestational age equal to or greater than 35 weeks); birth weight over 2,500 grams; exclusive breastfeeding. Exclusion criteria: infant parents' unwillingness to participate in the study.

Intervention groups
First intervention group: Intervention will performed in a quiet, bright room, on the bed, and in a position where the infant is lying back and quite relaxed. The researcher holds the baby's heel with his left hand and gently massage the area in each leg for 15 minutes (a total of 30 minutes for both legs) with his right hand. The intervention will done once a day and olive oil will be used to facilitate massage. Second intervention group: In this group, massage begins with the touch of the lower extremity and from the ankle (except soles of the feet) to the knee and groin. The umbilical region will massaged rotatly. The chest and back will massaged with both hands.The baby's hands will massaged rotatly from the arm to the fingers. The palms, cheeks and lips are also gently massaged with the index finger. Massages for each infant will be once daily for 10-15 minutes. Control group: This group did not receive any intervention.

Main outcome variables
Physiological parameters; bilirubin level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20161210031328N11**
Registration date: **2020-01-06, 1398/10/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-06, 1398/10/16**
Update count: **0**

Registration date
2020-01-06, 1398/10/16

Registrant information

Name
Mahbobeh Sajadi

Name of organization / entity
Arak University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-21, 1398/09/30

Expected recruitment end date
2020-03-20, 1399/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of foot reflexology and body massage on physiological parameters and bilirubin levels in neonates under photo therapy

Public title
Comparison of the effect of reflexology and body massage on physiological parameters and bilirubin levels in neonates under photo therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
No underlying, congenital and infectious diseases Term infants (gestational age equal to or greater than 35 weeks) Birth weight over 2,500 grams Exclusive breastfeeding
Exclusion criteria:
Infant parents' unwillingness to participate in the study
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **51**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants were individually divided into three groups of first intervention (reflexology), second intervention (body massage) and control group using blocked randomization. In this study, dice will be considered as a randomization tool. For making sequences, "A" letter will be assigned to the first group, "B" letter will be assigned to the second group, and the "C" letter will be assigned to the third group. Participants will not know allocation of samples to interventions and control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Data analyzer will not know how individuals are assigned to the interventions and control groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Basij Sq., Sardasht Region
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2019-10-13, 1398/07/21
Ethics committee reference number
IR.ARAKMU.REC.1398.200

Health conditions studied

1

Description of health condition studied
Jaundice
ICD-10 code
P59.9
ICD-10 code description
Neonatal jaundice, unspecified

Primary outcomes

1

Description
Percentage of arterial oxygen saturation (O2 saturation)
Timepoint
Before intervention and one day after intervention
Method of measurement
cardio set ARDP 10 vital signs monitoring system (made in Iran)

2

Description
Heart rate
Timepoint
Before intervention and one day after intervention
Method of measurement
cardio set ARDP 10 vital signs monitoring system (made in Iran)

3

Description
Respiratory rate
Timepoint
Before intervention and one day after intervention
Method of measurement

hs43 chronometer (made in China).

Secondary outcomes

1

Description
Bilirubin level
Timepoint
Before intervention and one day after intervention
Method of measurement
Serum bilirubin (wrist venous blood sample) measured by photometry.

Intervention groups

1

Description
First intervention group: Intervention will performed in a quiet, bright room, on the bed, and in a position where the infant is lying back and quite relaxed. The researcher holds the baby's heel with his left hand and gently massage the area in each leg for 15 minutes (a total of 30 minutes for both legs) with his right hand. The intervention will done once a day and olive oil will be used to facilitate massage.
Category
Treatment - Other

2

Description
Second intervention group: In this group, massage begins with the touch of the lower extremity and from the ankle (except soles of the feet) to the knee and groin. The umbilical region will massaged rotatly . The chest and back will massaged with both hands.The baby's hands will massaged rotatly from the arm to the fingers. The palms, cheeks and lips are also gently massaged with the index finger. Massages for each infant will be once daily for 10-15 minutes.
Category
Treatment - Other

3

Description
Control group: routine care
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Asgarieh Hospital
Full name of responsible person
Mohammadreza Shahnaser
Street address
Asgarieh St., Soroush St.
City
Isfahan
Province
Isfehan
Postal code
8199753966
Phone
+98 31 3225 0041
Email
info@askariehospital.com

2

Recruitment center
Name of recruitment center
Imam Hosseain Hospital
Full name of responsible person
Mehrdad Memarzadeh
Street address
Imam Hossein Hospital, Imam Khomeini St.
City
Isfahan
Province
Isfehan
Postal code
8195163381
Phone
+98 31 3386 6266
Email
emamhossein_hospital@mui.ac.ir

3

Recruitment center
Name of recruitment center
Goldis Hospital
Full name of responsible person
Mohammad Ebne-hejazi
Street address
Goldis Hospital, Goldis Town
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Shahin Shahr
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3526 0801
Email
goldis_hospital@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address

Arak University of Medical Sciences, Basij Sq., Sardasht Region

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3819693345

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info@arakmu.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Arak 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
Arak University of Medical Sciences

Full name of responsible person
Zahra Jazayeri

Position
Student

Latest degree
Bachelor

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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Position
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Latest degree
Bachelor

Other areas of specialty/work
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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
Not applicable

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

Part of data, such as information on the main outcome can be shared.

When the data will become available and for how long

12 months after the publishing of the results.

To whom data/document is available

Researchers in academic and scientific institutions.

Under which criteria data/document could be used

Scientific purposes.

From where data/document is obtainable

Zahra Jazayeri za.jazayeri48@gmail.com

What processes are involved for a request to access data/document

2 to 3 working days.

Comments