

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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)

Phone

+98 86 3402 0115

Email address

m.sajadi@arakmu.ac.ir

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

Isfahan

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

Isfahan

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

City

Shahin Shahr

Province

Isfahan

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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Arak

Province

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3819693345

Phone

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Email

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

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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Latest degree

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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